

EXHIBIT 2

Page 1

UNITED STATES DISTRICT COURT.
DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN,
AND IRBESARTAN PRODUCTS
LIABILITY LITIGATION

MDL NO. 2875

HON. ROBERT B. KUGLER

THIS DOCUMENT RELATES TO:

In Re: Valsartan, Losartan and
Irbesartan Products Liability
Litigation,
Case No. 1:19-md-2875-RBK

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HIGHLY CONFIDENTIAL REMOTE VIDEOTAPED DEPOSITION
OF LAURA PLUNKETT
THURSDAY, JANUARY 12, 2023
9:29 a.m.

Witness' Location:

Houston, Texas

TRANSCRIPT of the stenographic notes of the
proceedings in the above-entitled matter as taken by
and before DAVID LEVY, a Certified Court Reporter and
Notary Public of the State of New Jersey, held
remotely over the Internet, on Thursday, January 12,
2023, commencing approximately 9:29 in the forenoon,
pursuant to Notice.

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<div>Page 2</div> <div>1 A P P E A R A N C E S:</div> <div>2 (All appearances are remote via Zoom conference.)</div> <div>3</div> <div>4 ON BEHALF OF THE PLAINTIFFS:</div> <div>5 ADAM M. SLATER, ESQ.</div> <div>6 MAZIE SLATER KATZ & FREEMAN, LLC</div> <div>7 103 Eisenhower Parkway</div> <div>8 Roseland, New Jersey 07068</div> <div>9 973-228-9898</div> <div>10 aslater@mazieslater.com</div> <div>11</div> <div>12 ON BEHALF OF THE PLAINTIFFS</div> <div>13 BRETT VAUGHN, ESQ.</div> <div>14 MELISHA VELEZ, ESQ.</div> <div>15 THE HOLLIS LAW FIRM</div> <div>16 8101 College Boulevard, Suite 250</div> <div>17 Overland Park, Kansas 66210</div> <div>18 913-385-9400</div> <div>19</div> <div>20 ON BEHALF OF THE PLAINTIFFS:</div> <div>21 STEVE LEVIN, ESQ.</div> <div>22 DANIEL NIGH, ESQ.</div> <div>23 LEVIN PAPANTONIO RAFFERTY PROCTOR BUCHANAN O'BRIEN</div> <div>24 BARR MONGEY P.A.</div> <div>25 316 South Baylen Street</div> <div>Pensacola, Florida 32502</div> <div>850-435-7003</div> <div>slevin@levinlaw.com</div> <div>dnigh@levinlaw.com</div> <div>ON BEHALF OF DEFENDANT SCIEGEN PHARMACEUTICALS, INC.</div> <div>KATHLEEN E. KELLY, ESQ.</div> <div>HINSHAW & CULBERTSON LLP</div> <div>53 State Street, 27th Floor</div> <div>Boston, Massachusetts 02109</div> <div>617-213-7047</div> <div>kekelly@hinshawlaw.com</div> <div></div> <div></div> <div></div> <div></div> <div></div>	<div>Page 4</div> <div>1 A P P E A R A N C E S (Cont.d):</div> <div>2 ON BEHALF OF THE DEFENDANT MYLAN N.V.</div> <div>3 FRANK H. STOY, ESQ.</div> <div>4 PIETRAGALLO, GORDON, ALFANO, BOSICK & RASPANTI, LLP</div> <div>5 301 Grant Street, 38th Floor</div> <div>6 Pittsburgh, Pennsylvania 15219</div> <div>7 412-263-4397</div> <div>8 fhs@pietragallo.com</div> <div>9 mbcatallo@pietragallo.com</div> <div>10</div> <div>11</div> <div>12 FOR THE DEFENDANT TORRENT PHARMACEUTICALS</div> <div>13 BRITTNEY NAGLE, ESQ.</div> <div>14 KIRKLAND & ELLIS, LLP</div> <div>15 601 Lexington Avenue</div> <div>16 New York, New York 10022</div> <div>17 212-909-3344</div> <div>18 brittney.nagle@kirkland.com</div> <div>19</div> <div>20</div> <div>21 FOR THE DEFENDANT HUMANA</div> <div>22 MEGAN A. ZMICK, ESQ.</div> <div>23 FALKENBERG IVES, LLP</div> <div>24 230 West Monroe, Suite 2220</div> <div>25 Chicago, Illinois 60606</div> <div>312-566-4801</div> <div>maz@falkenbergives.com</div> <div>FOR THE DEFENDANT ALBERTSON'S LLC</div> <div>CHRISTOPHER B. HENRY, ESQ.</div> <div>BUCHANAN INGERSOLL & ROONEY, P.C.</div> <div>Carillon Tower</div> <div>227 West Trade Street, Suite 600</div> <div>Charlotte, North Carolina 28202-2601</div> <div>704-444-3300</div> <div>ALSO PRESENT:</div> <div>LEE BOWRY, Videographer</div> <div>GREGG HOLDERMAN, Concierge</div> <div></div> <div></div> <div></div> <div></div> <div></div>
<div>Page 3</div> <div>1 A P P E A R A N C E S (Cont'd):</div> <div>2 ON BEHALF OF THE DEFENDANTS HETERO LABS AND HETERO</div> <div>3 DRUGS:</div> <div>4 ERIC ABRAHAM, ESQ.</div> <div>5 JOHN C. BOBBER, JR.</div> <div>6 HILL WALLACK, LLP</div> <div>7 21 Roszel Road</div> <div>8 Princeton, New Jersey 08540</div> <div>9 609-924-0808</div> <div>10 eabraham@hillwallack.com</div> <div>11 jbobber@hillwallack.com</div> <div>12</div> <div>13 ON BEHALF OF THE DEFENDANT TEVA</div> <div>14 PHARMACEUTICALS USA, INC.</div> <div>15 STEVEN M. HARKINS, ESQ.</div> <div>16 VICTORIA DAVIS LOCKARD, ESQ.</div> <div>17 GREENBERG TRAURIG, LLP</div> <div>18 3333 Piedmont Road NE, Suite 2500</div> <div>19 Atlanta, Georgia 30305</div> <div>20 678-553-7392</div> <div>21 harkins@gtlaw.com</div> <div>22 lockardv@gtlaw.com</div> <div>23 -and-</div> <div>24 CHRISTINE I. GANNON, ESQ.</div> <div>25 WALSH PIZZI O'REILLY FALANGA LLP</div> <div>Three Gateway Center</div> <div>One Mulberry Street, 15th Floor</div> <div>Newark, New Jersey 07102</div> <div>ON BEHALF OF DEFENDANT ZHP</div> <div>JESSICA D. MILLER, ESQ.</div> <div>ANNA BRIER, ESQ.</div> <div>TARA KOHLI, ESQ.</div> <div>SKADDEN ARPS SLATE MEAGHER & FLOM LLP</div> <div>1440 New York Avenue, N.W.</div> <div>Washington, D.C. 20005</div> <div>212-371-7134</div> <div>anna.brier@skadden.com</div> <div>tara.kohli@skadden.com</div> <div>jessica.miller@skadden.com</div> <div>-and-</div> <div>BRIAN BAGGETTA, ESQ.</div> <div>SKADDEN ARPS SLATE MEAGHER & FLOM LLP</div> <div>One Manhattan West</div> <div>New York, New York 10001</div> <div>202-371-7209</div> <div>brian.baggetta@skadden.com</div>	<div>Page 5</div> <div>1 -----INDEX-----</div> <div>2 WITNESS EXAMINATION PAGE</div> <div>3 LAURA M. PLUNKETT MS. MILLER 9</div> <div>4 MR. HARKINS 284</div> <div>5 MS. NAGLE 321</div> <div>6 MR. VAUGHN 323</div> <div>7 MS. MILLER 325</div> <div>8</div> <div>9 PLUNKETT EXHIBITS FOR IDENT.</div> <div>10 Exhibit 1 Expert report of Laura M. 53</div> <div>11 Plunkett, Ph.D., DABT, dated</div> <div>12 10/31/22</div> <div>13 Exhibit 2 FDA press release dated 69</div> <div>14 7/13/18</div> <div>15</div> <div>16 Exhibit 3 FDA statement dated 8/30/18 72</div> <div>17</div> <div>18 Exhibit 4 FDA statement dated 1/5/19 83</div> <div>19 from Scott Gottlieb, M.D.</div> <div>20</div> <div>21 Exhibit 5 Boerner article from Chemical 94</div> <div>22 and Engineering News dated</div> <div>23 4/20/20</div> <div>24</div> <div>25 (Continued on following page.)</div>

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<p style="text-align: right;">Page 6</p> <p>1 -----INDEX-----</p> <p>2 PLUNKETT EXHIBITS (Cont'd.) FOR IDENT.</p> <p>3 Exhibit 6 E-Mail chain Bates numbered 180</p> <p>4 ZHP00492652 through 92659</p> <p>5</p> <p>6 Exhibit 7 E-Mail chain Bates numbered 187</p> <p>7 ZHP02118712 through 8731</p> <p>8</p> <p>9 Exhibit 8 E-Mail chain Bates numbered 190</p> <p>10 ZHP02118681 through 8711</p> <p>11</p> <p>12 Exhibit 9 Transcript of deposition of 197</p> <p>13 Min Li, Ph.D.</p> <p>14</p> <p>15</p> <p>16 (Continued on following page.)</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>	<p style="text-align: right;">Page 8</p> <p>1 VIDEOGRAPHER: Stand by, everyone.</p> <p>2 We'll be underway in about ten seconds.</p> <p>3 Good morning. We are going on the</p> <p>4 record at 9:29 a.m. on January 12, 2023. Please note</p> <p>5 that this deposition is being conducted virtually.</p> <p>6 Quality of recording depends on the quality of camera</p> <p>7 and about the connection of participants. What is</p> <p>8 spoken from the witness and heard on screen is what</p> <p>9 will be recorded. Audio and video recording will</p> <p>10 continue to take place unless all parties agree to go</p> <p>11 off the record.</p> <p>12 This is media unit 1 of the video</p> <p>13 recorded deposition of Dr. Laura M. Plunkett in the</p> <p>14 matter of in re, Valsartan, Losartan and Irbesartan</p> <p>15 products liability litigation filed in the United</p> <p>16 States District Court for the District of New Jersey,</p> <p>17 Camden vicinage, MDL number 2875.</p> <p>18 My name is Lee Bowery, representing</p> <p>19 Veritext New Jersey. I am the videographer. The</p> <p>20 court reporter is David Levy, and the concierge is</p> <p>21 Gregg Holderman, both also with Veritext.</p> <p>22 I am not related to any party in this</p> <p>23 action, nor am I financially interested in the</p> <p>24 outcome. If there are any objections to proceeding,</p> <p>25 please state them at this time.</p>
<p style="text-align: right;">Page 7</p> <p>1 -----INDEX-----</p> <p>2 PLUNKETT EXHIBITS (Cont'd.) FOR IDENT.</p> <p>3 Exhibit 10 Invoice dated December 2022 266</p> <p>4 on BioPolicy Solutions</p> <p>5 letterhead, addressed to</p> <p>6 Pendley, Baudin & Coffin</p> <p>7</p> <p>8 Exhibit 11 Plaintiffs' Objections and 287</p> <p>9 Responses to Defendants'</p> <p>10 Notice of Deposition of Laura</p> <p>11 Plunkett</p> <p>12</p> <p>13 Exhibit 12 Transcript of deposition of 313</p> <p>14 Phillip Russ</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>	<p style="text-align: right;">Page 9</p> <p>1 Having heard none, counsel attending</p> <p>2 remotely will be noted on the stenographic record.</p> <p>3 Will the court reporter please swear in the witness</p> <p>4 and then counsel may proceed.</p> <p>5 L A U R A M. P L U N K E T T , having been</p> <p>6 duly sworn by the Notary Public, was examined</p> <p>7 and testified as follows:</p> <p>8 MS. MILLER: May I proceed?</p> <p>9 EXAMINATION BY</p> <p>10 MS. MILLER:</p> <p>11 Q. Good morning, Dr. Plunkett. Thank you</p> <p>12 for your patience this morning. Can you just please</p> <p>13 state your full name for the record.</p> <p>14 A. Laura Massey Plunkett.</p> <p>15 Q. Great. I know you've been deposed many</p> <p>16 teams, and so given especially that we have lost a</p> <p>17 little time this morning, I am going to forego</p> <p>18 providing you with the rules of depositions. I think</p> <p>19 we all know them, and I'm just going to get straight</p> <p>20 into the matters we're here to discuss today. Does</p> <p>21 that sound good?</p> <p>22 A. That's fine.</p> <p>23 Q. Great. You understand that I'm here to</p> <p>24 discuss opinions you're rendering as an expert for</p> <p>25 Plaintiffs in the MSP Valsartan case, correct?</p>

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<p style="text-align: right;">Page 10</p> <p>1 A. Yes.</p> <p>2 Q. And do you know who MSP is?</p> <p>3 A. No.</p> <p>4 Q. Do you know who the Plaintiff is in this</p> <p>5 matter?</p> <p>6 A. The names of the Plaintiffs, no.</p> <p>7 Q. What's your understanding of your role</p> <p>8 in this litigation?</p> <p>9 A. I was engaged to provide opinions</p> <p>10 related to -- it's in my report, related to the</p> <p>11 toxicology or genotoxicology of the impurities found</p> <p>12 in Valsartan that are known generally as</p> <p>13 nitrosamines. And in this particular deposition, two</p> <p>14 specific ones. MDMA and NDEA. I'm just going to</p> <p>15 abbreviate them.</p> <p>16 I was also asked to provide general</p> <p>17 regulatory opinions related to the way that these are</p> <p>18 generic drug products, the way the generic products</p> <p>19 are regulated generally by the FDA, the role and</p> <p>20 responsibilities of manufacturers of both active</p> <p>21 pharmaceutical ingredients, and if we can agree, I'll</p> <p>22 call them APIs, and then what I call finished dose</p> <p>23 products, so that would be the products that are</p> <p>24 actually the subject of the, what I call Abbreviated</p> <p>25 New Drug Applications, or ANDAs, in this case.</p>	<p style="text-align: right;">Page 12</p> <p>1 the presence of impurities increases the risk of</p> <p>2 cancer for Valsartan users?</p> <p>3 MR. VAUGHN: Object to form.</p> <p>4 A. Are you asking me have I done an</p> <p>5 independent risk calculation or done a risk</p> <p>6 assessment to come up with a level of cancer risk, is</p> <p>7 that what you're asking?</p> <p>8 Q. Let me put it more simply. I believe</p> <p>9 you testified that the presence of impurities in</p> <p>10 Valsartan increases the risk of cancer, right?</p> <p>11 A. Yes.</p> <p>12 Q. Do you have an opinion on how much it</p> <p>13 increases the risk of cancer?</p> <p>14 MR. VAUGHN: Object to form.</p> <p>15 A. I don't have a -- I haven't done --</p> <p>16 that's why I asked the question that I did. I mean,</p> <p>17 too answer that question, I would typically say, have</p> <p>18 I calculated a -- a risk value independently, and I</p> <p>19 have not done that. I think that's what you're</p> <p>20 asking me. That's how I would describe what you're</p> <p>21 asking for. And so I have not done that. I'm aware</p> <p>22 that there have been others. If you go to the</p> <p>23 toxicology literature and even to different documents</p> <p>24 off the -- produced by different regulatory</p> <p>25 authorities, the issue of increased risk can be a</p>
<p style="text-align: right;">Page 11</p> <p>1 Q. Are you offering a causation opinion?</p> <p>2 A. No, I'm not. I'm not a causation expert</p> <p>3 as it relates to injuries, if that's what you mean by</p> <p>4 causation.</p> <p>5 Q. Are you offering an opinion that the use</p> <p>6 of Valsartan contaminated with NDMA can cause cancer?</p> <p>7 A. I believe I did have that on my report</p> <p>8 as it relates to what was known or is known and has</p> <p>9 been known over the decades about the risks posed by</p> <p>10 Valsartan. I have a couple of paragraphs where I</p> <p>11 talk about sort of the -- both the general</p> <p>12 toxicologic community believes is true or knows is</p> <p>13 true about the risks, the cancer risks posed by</p> <p>14 exposure to the impurities of Valsartan.</p> <p>15 Q. Are you offering an opinion that the</p> <p>16 levels of NDMA contained in Valsartan can cause</p> <p>17 cancer?</p> <p>18 MR. VAUGHN: Object to form.</p> <p>19 A. I don't believe I have that specific</p> <p>20 opinion, no. But I certainly do have opinions in the</p> <p>21 report, if you've read it, that I talk about the fact</p> <p>22 that is presence of the impurities increases the risk</p> <p>23 for cancer generally, and that the poses a hazard and</p> <p>24 puts patient safety at risk.</p> <p>25 Q. Have you quantified how much you believe</p>	<p style="text-align: right;">Page 13</p> <p>1 specific issue for a specific exposure pattern. And</p> <p>2 I'm not specific causation, so I haven't done those</p> <p>3 kinds of calculations.</p> <p>4 Q. So if you haven't calculated the risk</p> <p>5 and value, how do you know there is actually an</p> <p>6 increase in risk?</p> <p>7 MR. VAUGHN: Object to form.</p> <p>8 A. Because of the -- what is understood</p> <p>9 about cancer and these particular compounds. Do you</p> <p>10 want me to explain?</p> <p>11 Q. Have you determined whether the dose of</p> <p>12 NDMA and NDEA in Valsartan was sufficient to increase</p> <p>13 the risk of cancer?</p> <p>14 MR. VAUGHN: Object to form.</p> <p>15 A. The answer -- a you're asking a question</p> <p>16 that has to do with specific -- a specific situation</p> <p>17 for specific person maybe taking Valsartan at a</p> <p>18 specific dose over a period of time. That's the best</p> <p>19 way to answer that question. Or that's actually the</p> <p>20 scientifically defensible way to answer the question.</p> <p>21 Do you want me to explain a little bit why I am</p> <p>22 answering that way? I'm happy to give you a little</p> <p>23 background on risk assessment and how it applies.</p> <p>24 Q. No, because my question really is, how</p> <p>25 much Valsartan would a person have to take to</p>

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<p style="text-align: right;">Page 14</p> <p>1 increase their risk of cancer?</p> <p>2 MR. VAUGHN: Object to form.</p> <p>3 A. Well, it's not the Valsartan. It's</p> <p>4 taking in the impurities of the Valsartan. So the</p> <p>5 Valsartan itself, by itself, if you were to have a</p> <p>6 hundred percent pure Valsartan, that's not the</p> <p>7 compound that I'm referring to that will increase</p> <p>8 risk of cancer; however, it's the impurities in the</p> <p>9 Valsartan, and nitrosamines, specifically NDMA and</p> <p>10 NDEA, that are in the compound; and we assume when</p> <p>11 you take Valsartan in this case, the evidence in the</p> <p>12 date that has shown you're taking in those</p> <p>13 impurities. It's the presence of those impurities</p> <p>14 that are increasing the risk of cancer. If they made</p> <p>15 Valsartan without those impurities, the cancer risk</p> <p>16 is not there.</p> <p>17 Q. Understood. But my question is, if</p> <p>18 somebody took one Valsartan pill during the class</p> <p>19 period that had these impurities, did that person</p> <p>20 have any increased risk of cancer?</p> <p>21 MR. VAUGHN: Object to form.</p> <p>22 A. That's beyond the scope of what I did,</p> <p>23 thank you. I did not do calculations based on</p> <p>24 exposure assessments. It's my understanding that</p> <p>25 there are other experts in this litigation that are</p>	<p style="text-align: right;">Page 16</p> <p>1 with the drug. And as a result of that work, I'm</p> <p>2 saying to you that it's very clear as a toxicologist,</p> <p>3 pharmacologist, risk assessor, someone who works in</p> <p>4 regulatory affairs, that the presence of this</p> <p>5 ingredient in Valsartan, where there is no known safe</p> <p>6 dose generally of these impurities, that it applies</p> <p>7 to any particular individual, because you have to do</p> <p>8 this on an individual basis based upon their exposure</p> <p>9 assessment; but generally the statement is that it</p> <p>10 increases the risk of cancer. It increases the risk</p> <p>11 in that particular person that you may want to</p> <p>12 consider that they would have an outcome of cancer.</p> <p>13 And then from that, the role of the</p> <p>14 specific causation expert or the risk assessors in</p> <p>15 the litigation would be to talk about the specific</p> <p>16 level of exposure. So that's why I'm saying that's</p> <p>17 beyond what I did. I looked at this from the aspect</p> <p>18 of the regulatory expert, as a toxicologist, what do</p> <p>19 I know, and I know that these were probable human</p> <p>20 carcinogens. They are not supposed to be in the</p> <p>21 Valsartan, or the presence of them as very potent</p> <p>22 genotoxins increases the risk of cancer.</p> <p>23 Q. Your risk opinion is completely</p> <p>24 untethered to any dose?</p> <p>25 MR. VAUGHN: Object to form.</p>
<p style="text-align: right;">Page 15</p> <p>1 either what I call risk assessors or specific</p> <p>2 causation experts that are doing those types of</p> <p>3 assessments. And that was beyond the scope of what I</p> <p>4 did. I think if you read my report, I hope you</p> <p>5 understand what it is that I've done, based upon my</p> <p>6 description of the facts and the other information.</p> <p>7 Q. You did say you're testifying that the</p> <p>8 presence of impurities in Valsartan increases the</p> <p>9 risk of cancer. And I'm asking what is the minimal</p> <p>10 doses at which that happens?</p> <p>11 A. And again, I'm answering it to you, I</p> <p>12 already have, in the literature -- this is where I</p> <p>13 need to explain. I'm not trying to be nonresponsive,</p> <p>14 but let me just step back a second and state that if</p> <p>15 you remember, you understand as I said that I believe</p> <p>16 that NDMA and NDEA have been identified by</p> <p>17 authoritative bodies as carcinogens, probable human</p> <p>18 carcinogens, based on the data that's there. If</p> <p>19 you -- with that in mind, and looking at what this</p> <p>20 drug, what the FDA has said and what other, how you</p> <p>21 would approach risk assessment for these kinds of</p> <p>22 products in the context of pharmaceutical risk</p> <p>23 assessment or risks are looked at in the context of</p> <p>24 benefits, in this case, you're talking about how does</p> <p>25 the risk of cancer balance against what is going on</p>	<p style="text-align: right;">Page 17</p> <p>1 A. What do you mean by "untethered to</p> <p>2 dose"? Are you asking --</p> <p>3 Q. Are you saying --</p> <p>4 A. -- whether it would change depending</p> <p>5 upon whether it was detectable or not detectable?</p> <p>6 Q. No. I'm asking, are you testifying that</p> <p>7 that the impurities increase the risk of cancer</p> <p>8 regardless of the dose of Valsartan with the</p> <p>9 impurities that a person took?</p> <p>10 MR. VAUGHN: Object to form.</p> <p>11 A. The way you're asking the question is</p> <p>12 what I'm having trouble with. So there's -- my</p> <p>13 opinions relate to whether or not, in the population</p> <p>14 of people that could be -- that were exposed to</p> <p>15 Valsartan, there an increased risk of cancer. It's a</p> <p>16 population-dependent -- just like FDA does, when they</p> <p>17 do assessments for drugs and look at risks, they look</p> <p>18 at it across generally the population of people</p> <p>19 taking the drug. So that's what I'm stating to you</p> <p>20 about risk, increased risk.</p> <p>21 Then, where you're going, when you're</p> <p>22 talking about the dose, then you have to look at what</p> <p>23 different exposure patterns were for individuals.</p> <p>24 FDA has said, if you read their different statements</p> <p>25 about the presence of these impurities in Valsartan,</p>

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<p style="text-align: right;">Page 18</p> <p>1 that these particular impurities are ones that are 2 known to be associated with the risk of cancer, and 3 that's what I'm saying. These increase the risk of 4 cancer if you take them. They are associated with 5 that risk. And then from there, for any one 6 individual person, which is beyond the scope of what 7 I did, others are doing that, they can tell you for 8 that individual at what that risk might be in terms 9 of quantifying. Because I think that's what you're 10 asking. I think you're asking to quantify. 11 Q. Do you have an opinion as to whether 12 someone who took one Valsartan pill during the period 13 when it contained an impurity, whether that person is 14 at an increased risk of cancer? 15 MR. VAUGHN: Object to form. 16 A. That is not the opinion I've stated in 17 my report, or addressed, because that was beyond the 18 scope of what I was asked to do. Again, it's my 19 understanding that others in the litigation are 20 handling the issues related to daily doses of 21 Valsartan and the doses of the impurities and how 22 those relate to individual injuries. 23 Q. Do you consider yourself to be an FDA 24 expert? 25 A. I consider myself to be an expert in the</p>	<p style="text-align: right;">Page 20</p> <p>1 A. I don't have an exact date. If you look 2 at my billing, that -- I don't have bills in front of 3 me but I know you've been provided those. Those give 4 you an idea of the dates that are involved with my 5 work on the case and I would have been contacted or 6 hired sometime before that, sometime probably a year 7 before the first work was done. 8 Q. A year before? 9 A. Sometime during the year before the 10 first work was done. I can't give you an exact date. 11 Q. So you don't recall when you -- whether 12 it was 2022, when you were first contacted? 13 A. Oh, it was not 2022, no. It would have 14 been before that, during COVID, so in fact, again, I 15 don't have an exact recollection but my -- I have a 16 lot of cases like this one, that have been long 17 delayed from the typical time period because of the 18 issues related to the pandemic and the way courts 19 have moved much more slowly during that time. 20 Q. Do you recall when you agreed to serve 21 as an expert? 22 A. If you have the -- I believe I signed a 23 confidentiality for documents, so that would be right 24 around the time or right before the time -- right 25 after the time that I agreed to serve, yes.</p>
<p style="text-align: right;">Page 19</p> <p>1 FDA regulations as they apply to products that are 2 currently regulated by the U.S. FDA, yes. 3 Q. Have you ever described yourself as an 4 FDA expert? 5 A. It's possible. I don't know if I've 6 used those exact words, if that's what you're asking 7 me. I think in my report, I talk about being an 8 expert at FDA regulated products or the regulation of 9 products. 10 Q. Do you recall sitting here whether 11 you've ever described yourself as an FDA expert? 12 A. Are you asking me if I ever used just 13 those words? I don't know, it's possible I did. 14 Q. Have you ever worked at FDA? 15 A. I've never been an employee of the FDA, 16 no. 17 Q. Have you ever been a consultant for the 18 FDA? 19 A. A hired consultant, no. I've 20 represented clients before FDA before. And I 21 interface with them. But I am not an employee, I've 22 never been an employee, and I've never been hired as 23 a consultant, no. 24 Q. When were you first contacted about 25 potentially serving as an expert in this litigation?</p>	<p style="text-align: right;">Page 21</p> <p>1 Q. And -- 2 A. And I don't have that in front of me 3 this morning. You should have that in your files, I 4 would think. 5 Q. Between being asked to serve as an 6 expert and agreeing to serve as an expert, did you do 7 research on Valsartan? 8 A. No, because I had already done it 9 years before that. I was -- to explain that, I was 10 well aware of what was going on with Valsartan from 11 the time that it first appeared in what I called the 12 trade press back in 2018, and there was first 13 knowledge -- I was aware of the fact that there had 14 been recalls, that the FDA was addressing the issue 15 and it's -- the reason I was aware of it is because 16 I'm a cardiovascular pharmacologist as part of my 17 expertise, and I have an interest in following drugs 18 in the classes that are part of my very specific 19 training and experience. 20 Q. Have you ever published any articles 21 about Valsartan? 22 A. No, I have not. Although I have 23 published articles related to the role of the 24 angiotensin system in control of the autonomic 25 nervous system included blood pressure.</p>

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<p style="text-align: right;">Page 22</p> <p>1 Q. Have you ever published any articles 2 about nitrosamines? 3 A. No, I have not. 4 Q. Have you ever given any speeches about 5 Valsartan? 6 A. No, I have not. 7 Q. Have you ever give any speeches about 8 nitrosamines? 9 A. I've never given a speech that was only 10 on nitrosamines, but certainly nitrosamines are 11 compounds that I may have had mentioned in speeches 12 where I talk about cancer, cancer risk assessment. 13 Q. Have you ever consulted in connection 14 with a product that contained NDMA or NDEA prior to 15 this litigation? 16 A. I don't believe it was related to 17 product, no. 18 Q. What do you mean by that? 19 A. So NDMA and NDEA, I've looked at the 20 issues that cancer was developed from nitrosamines in 21 the past, and I've looked at the animal data in the 22 past, back when some of those studies first appeared 23 I think in the '90s, to early 2000s. So I have 24 looked at the data related to these compounds before, 25 it's my understanding that, you know, I mean, my</p>	<p style="text-align: right;">Page 24</p> <p>1 A. I don't -- I'm not a lobbyist. What do 2 you mean by lobbying? 3 Q. Have you ever done any lobbying? 4 A. I'm not a lobbyist. So are you asking 5 me have I ever -- ever argued or had a meeting where 6 I've taken a position one way or the other, is that 7 what you mean, as a scientist? Because I have not, 8 no. 9 Q. Have you ever worked with a company that 10 manufactured a product using DMF? 11 A. I have no idea. 12 Q. Have you ever advised any companies 13 about the risks of degradation of DMF? 14 A. Not that I can recall, no. 15 Q. When did you first have knowledge that 16 DMF can degrade into diethylamine? 17 MR. VAUGHN: Objection, foundation. 18 A. So, I don't know that I can answer that 19 with any clarity, not knowing, not being able to say 20 whether or not in the past I've ever reviewed 21 information on that. It's very possible I have in 22 the past, but it's never been something that's been 23 top of my head. Certainly I'm aware of it based upon 24 the reports I've read on -- from Dr. Hecht in this 25 case, and also from the top deposition testimony of</p>
<p style="text-align: right;">Page 23</p> <p>1 knowledge that these are kind of prototypical 2 carcinogens. If you want a positive control animal 3 study, NDMA for example would be a good positive 4 control to use when you're testing for cancer. 5 Q. Have you ever advised a company on the 6 risks associated with NDMA and NDEA? 7 A. No, I don't -- I've never had a client 8 who had those detected in their products. 9 Q. Have you ever worked with a solvent, 10 DMF, dimethylformamide? 11 A. Formamide. Can you please be more 12 specific? I think you said work. Did you say 13 "work"? What do you mean by "work," have I ever come 14 across it, have I ever given it to an animal, what 15 are you asking? 16 Q. Have you ever done any professional work 17 involving that solvent? 18 A. Well, it's still a really broad 19 question, I would argue, but certainly it is a 20 compound I've heard of before in my work but it isn't 21 that I've ever, like, drafted a toxicology profile or 22 done any specific testing where I've -- that's been 23 involved with that particular compound, no. 24 Q. Have you ever done any lobbying 25 involving a product that contains DMF?</p>	<p style="text-align: right;">Page 25</p> <p>1 some of the people, the witnesses for ZHP in the 2 case. 3 Q. Prior to being contacted about serving 4 as an expert in this litigation, did you personally 5 have knowledge that DMF could degrade into 6 diethylamine? 7 MR. VAUGHN: Object to form. 8 A. I don't recall ever having that as 9 something that I could say that I was asked about. 10 So, I mean, I -- that's the best I can answer it for 11 you. It's not been a focus of any work that I can 12 recall in the past. 13 Q. Have you ever been, prior to being 14 contacted about serving as an expert in this 15 litigation, did you ever have knowledge that the TEA 16 process used by ZHP could lead to the formation of 17 NDEA? 18 MR. VAUGHN: Object to form. 19 A. No, because I wasn't aware of ZHP's TEA 20 process until discovery documents in this case became 21 available. That's when I became aware of what it was 22 that they had been done in terms of understanding how 23 they produced thee product. 24 Q. Prior to being contacted about serving 25 as an expert in this case, did you personally have</p>

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<p style="text-align: right;">Page 26</p> <p>1 knowledge about how any chemical process could lead 2 to the formation of NDEA? 3 MR. VAUGHN: Object to form. 4 A. NDEA? Um -- yes. I mean, I have 5 reviewed the toxicology literature over the years 6 related to these types of impurities and actually, in 7 the EPA projects I've worked on, on the carbon 8 contaminants in that particular case, which is a 9 little different than the FDA world. But yes, I have 10 reviewed the formation. 11 I have some -- in fact, the structures 12 that I put into my report come from one of my 13 textbooks, and I've reviewed that section and that 14 chapter of the textbooks several times in the past, 15 so I have that awareness. But I've never worked -- I 16 had not, you know, I have not developed a report 17 before for anyone, none of my clients ever approached 18 me to put together a tox profile on NDEA 19 specifically. So it's more general of understanding 20 and training based upon the toxicology training I've 21 had. 22 Q. Can NDEA be formed with tertiary amines, 23 or amines? 24 MR. VAUGHN: Objection, form, 25 foundation.</p>	<p style="text-align: right;">Page 28</p> <p>1 report and his description of some of these reports. 2 Q. When you talk about the exhibits used in 3 depositions, you're talking about the textbook that 4 you cite and the Tetrahedron article you cite? 5 MR. VAUGHN: Object to form. 6 A. That I mention in my report, yes. Those 7 are the two that I saw, they were described in the -- 8 by Dr. Hecht. But they have also described, they are 9 asked about within the deposition of one of the 10 witnesses or several of the witnesses for ZHP, the 11 depositions I read. 12 Q. Have you seen the Australian textbook 13 before serving as a expert in this litigation? 14 A. That was not one I had in my files, no. 15 Q. And had you seen the Tetrahedron article 16 before serving as an expert in this litigation? 17 A. I don't recall, but I don't know, based 18 on the number of years it's been since I've been 19 asked specifically these kinds of questions before by 20 any client. 21 Q. Are you a regular reader of the 22 Tetrahedron Journal? 23 MR. VAUGHN: Object to form. 24 A. What do you mean by "regular reader," do 25 you mean do I subscribe? Is that what you're asking?</p>
<p style="text-align: right;">Page 27</p> <p>1 A. So that's beyond the scope of what I -- 2 what I have done in terms of coming and being able to 3 understand or describe all of the ways it can be 4 formed. Certainly, I'll refer you to Dr. Hecht or 5 all the other experts, chemists in the litigation to 6 describe those kinds of details. There was an 7 understanding in this case based upon what processes 8 are described; and so if you want me to pull all 9 those documents, we can go back and look at what was 10 described in the particular documents related to this 11 case. 12 Q. Prior to reviewing the documents in this 13 case, did you have an understanding as to what sort 14 of amines were necessary and what alkyl groups were 15 necessary to form NDMA and NDEA? 16 MR. VAUGHN: Object to form and 17 foundation. 18 A. I can't say that I would have been able 19 to describe those for you in any detail before 20 looking at these documents, no. But I can tell you 21 that certainly, it is -- it was something that was 22 known in this literature, and I agree with that 23 because I went back and I looked at some of the 24 exhibits that were used in the depositions that talk 25 about the foreseeability, I've read Dr. Hecht's</p>	<p style="text-align: right;">Page 29</p> <p>1 Q. Sure. 2 A. It's not one I subscribe to, no. But it 3 certainly is a journal that comes up routinely when I 4 do searches for projects I've worked on. Tetrahedron 5 is one that publishes chemistry articles, 6 specifically those that deal with any toxic 7 compounds. 8 Q. Sitting here today, can you identify any 9 literature besides the Australian textbook and the 10 Tetrahedron article that addresses whether and when 11 DMF can degrade into diethylamine? 12 MR. VAUGHN: Object to form. 13 A. That was beyond the scope of what I did. 14 I didn't do that search. I could but I haven't done 15 that. I didn't feel I needed to do that in order to 16 provide the opinions I did in this case, because 17 there is a chemist that's doing that kind of work. 18 Q. You do provide an opinion that it was 19 known in 2012 that DMF could degrade into 20 diethylamine, right? 21 A. Yes, based on that -- I think if you 22 read my report I talked about the fact that when a 23 company is doing a risk assessment, part of that 24 would be search of the published literature to make 25 sure there is something that is out there that they</p>

<p style="text-align: right;">Page 30</p> <p>1 may not be aware of. So certainly, that's why I have 2 formed those opinions. If I was to do a risk 3 assessment for looking at something about the process 4 that's being used, I could look at what the potential 5 byproducts or degradation products or pathways that 6 could be affected by using this particular chemical 7 process. And so that's why those articles are 8 important, because it shows what was known at 9 different points of time and, most importantly, what 10 was known before the issues arose in this case about 11 the breakdown of -- or the use of the chemical 12 process that led to the presence of the NDMA and NDEA 13 in the Valsartan API.</p> <p>14 Q. The only published literature you cite 15 on those topics is published literature that was used 16 by Plaintiff counsel in depositions, correct?</p> <p>17 A. Yes. And again, that's because that was 18 beyond the scope of what I was asked to do. I was 19 not asked to be the chemist to address that specific 20 question in a complete and expansive manner.</p> <p>21 Q. So your opinion of this was widely 22 known, is based on documents that you obtained 23 through this litigation, correct?</p> <p>24 MR. VAUGHN: Object to norm.</p> <p>25 A. Well, depends. I also have -- I also --</p>	<p style="text-align: right;">Page 32</p> <p>1 A. So there's a stipulation document that's 2 in the paragraph, paragraph 45 in my report, where I 3 say that the lack of full evaluation of chemical 4 processes have been stipulated to by Defendants. So 5 evaluation -- full evaluation is what I'm talking 6 about in terms of the risk assessment.</p> <p>7 Q. Before you were contacted by Plaintiffs 8 in this litigation to serve as a paid expert, did you 9 do anything to warn the public about the use of 10 Valsartan that contained nitrosamine impurities?</p> <p>11 MR. VAUGHN: Object to form.</p> <p>12 A. So that's a really broad question. Are 13 you asking me a specific action that I took to maybe 14 write an article or are you asking me about 15 conversations? What are you asking me about?</p> <p>16 Q. I'm asking about it all.</p> <p>17 A. Well, I did have conversations with some 18 of my acquaintances, my colleagues, my family members 19 who were taking these drugs, who asked me questions 20 about it, when they saw the information in the 21 popular press.</p> <p>22 But I did not reach out to FDA, for 23 example. FDA was already aware, and I know this 24 because they were taking actions. I did not reach 25 out in any manner to any other type of -- other</p>
<p style="text-align: right;">Page 31</p> <p>1 well, not entirely -- are you asking me specifically 2 just about the issue of breakdown or the formation of 3 DMF for example, that's what you're asking me?</p> <p>4 Q. Correct.</p> <p>5 A. That would be true that -- because 6 again, that was beyond the scope of what I did 7 independently, but it's evidence that's important to 8 me in my opinions because one of the issues that you 9 have as a regulatory expert is understanding what a 10 company could or should have done if they had been 11 following all the regulations and been complying 12 fully with what they are required to do in the 13 literature to produce a human prescription drug 14 product.</p> <p>15 Q. I understand, but my question is really 16 simple. Your opinions of what the company could and 17 should have known are based on documents you obtained 18 in this litigation, correct?</p> <p>19 MR. VAUGHN: Objection.</p> <p>20 A. That and their own deposition testimony. 21 So the company -- ZHP company witnesses also agreed 22 to that issue, that these are things that could have 23 been known. They had not done a rigorous assessment.</p> <p>24 Q. What ZHP witness said that they did 25 not do a complete risk assessment?</p>	<p style="text-align: right;">Page 33</p> <p>1 company or -- but I certainly did have conversations 2 with individuals that reached out to me.</p> <p>3 Q. Did any family or friends ask you 4 whether they should continue taking their Valsartan 5 until there was -- until, you know, the market has 6 sufficient availability of alternatives?</p> <p>7 MR. VAUGHN: Object to form.</p> <p>8 A. That's not the question they asked, 9 because I'm not a physician. They asked me what did 10 I think about the issues and whether or not there was 11 a risk.</p> <p>12 Q. And what did you tell them?</p> <p>13 A. I told them I did believe there was a 14 risk based upon the fact that it is something that 15 wasn't meant to be in the products, and most 16 importantly, it increases the risk -- it's a potent 17 genotoxin and is known to increase the risk of 18 cancer; so in my opinion as a toxicologist, I would 19 not want to be taking a product that had these 20 impurities in it.</p> <p>21 Q. I've always heard the expression that 22 when it comes to toxicology, one of the major tenets 23 is that the dose is in the poison, or the poison is 24 in the dose. Is that a true -- an expression that's 25 used in toxicology?</p>

<p style="text-align: right;">Page 34</p> <p>1 MR. VAUGHN: Object to form.</p> <p>2 A. It is a term that's used. But there's a</p> <p>3 different -- there's a different sort of methodology</p> <p>4 or way for assessing risk and dose issues with cancer</p> <p>5 versus non-cancer. So that's absolutely the issue of</p> <p>6 threshold mechanism or a threshold existing for</p> <p>7 things that are doing, actively to produce effects</p> <p>8 that are not cancer.</p> <p>9 You can typically find a threshold if</p> <p>10 you do enough studies or do enough looking. However,</p> <p>11 for cancer risk assessment, if the assumption is that</p> <p>12 there is no threshold, so as a result, the dose makes</p> <p>13 the poison can apply, but it's not to the same extent</p> <p>14 or level as it does when you're talking non-cancer</p> <p>15 endpoints.</p> <p>16 Q. When you describe something as a potent</p> <p>17 genotoxin, in order to determine when it's a potent</p> <p>18 genotoxin, do you need to know what dose the person</p> <p>19 is exposed to?</p> <p>20 A. I'm not talking about as a person, I'm</p> <p>21 talking about based upon scientific evidence. And by</p> <p>22 "potent genotoxin," I'm describing the fact that the</p> <p>23 studies that have been done, genotoxicity studies are</p> <p>24 typically done in vitro. There are some in vivo</p> <p>25 studies but most of it's done in vitro. And in those</p>	<p style="text-align: right;">Page 36</p> <p>1 are unacceptable and are not supposed to be in the</p> <p>2 product.</p> <p>3 Q. Okay. When you said you advise them to</p> <p>4 switch to a drug that doesn't have those impurities,</p> <p>5 at that point, Valsartan had already been recalled</p> <p>6 and off the market, correct?</p> <p>7 MR. VAUGHN: Objection, form,</p> <p>8 foundation.</p> <p>9 A. So when the individuals, or an</p> <p>10 individual approaches me about asking these</p> <p>11 questions, this is something that has gone on for a</p> <p>12 while, that is true. But it's also my understanding</p> <p>13 that even though there had been recalls, there was a</p> <p>14 continually finding an issue with the presence of</p> <p>15 these impurities in the drug.</p> <p>16 And also, the other thing that I talked</p> <p>17 to individuals about is the fact that the presence of</p> <p>18 these impurities from my understanding and reading</p> <p>19 what FDA's investigations showed had to do with</p> <p>20 problems at the companies related to their</p> <p>21 manufacturing policy. So those kinds of</p> <p>22 conversations were had.</p> <p>23 It's more than just -- the questions I</p> <p>24 was asked was more as friends and people that I know</p> <p>25 coming to me and saying, "As a toxicologist, would</p>
<p style="text-align: right;">Page 35</p> <p>1 studies, when you compare, again when you look at</p> <p>2 cross-compounds, NDMA is often a positive control</p> <p>3 compound. It's used to make sure your assay is</p> <p>4 working properly.</p> <p>5 So in other words, it is reliably going</p> <p>6 to produce a genotoxic insult when you expose cells</p> <p>7 to it, and the potency has to do with the fact that</p> <p>8 you can get those kinds of DNA changes or changing</p> <p>9 mutations at very low exposure levels.</p> <p>10 Q. When your family members or friends came</p> <p>11 to you and asked if they were at an increased risk of</p> <p>12 cancer, did you tell them it depended on how much</p> <p>13 Valsartan, how much DMA they had consumed?</p> <p>14 MR. VAUGHN: Object to form, foundation.</p> <p>15 A. No one asked me to do that for them.</p> <p>16 They were more interested generally with the issue</p> <p>17 should they have a conversation with their doctor and</p> <p>18 consider whether or not they should be changing to a</p> <p>19 different drug. They didn't ask me, should they</p> <p>20 change; but my advice was, I mean, "Talk to your</p> <p>21 doctor, but if it was me, I would be talking to my</p> <p>22 doctor about switching to a drug that did not have</p> <p>23 that impurity, those impurities in them."</p> <p>24 Again, the FDA in themselves state that</p> <p>25 the NDMA and the NDEA in these nitrosamine impurities</p>	<p style="text-align: right;">Page 37</p> <p>1 this be something that you would want to be exposed</p> <p>2 to, should I worry about this?" And I said, "I would</p> <p>3 worry about it. It's something that you don't want</p> <p>4 to take, it's not supposed to be there, there are</p> <p>5 potentially alternatives, but you have to talk to</p> <p>6 your doctor because I'm not a physician."</p> <p>7 So I didn't say, "Please change to this,</p> <p>8 or please change to that."</p> <p>9 Q. Right. But by the time they came to</p> <p>10 you, they could no longer purchase Valsartan because</p> <p>11 it had been recalled, correct?</p> <p>12 MR. VAUGHN: Object to form, foundation.</p> <p>13 A. Well, I can't tell you whether or not</p> <p>14 anybody still had it in their possession. If</p> <p>15 somebody had been on Valsartan for a while they may</p> <p>16 have still had the drug in their -- that's beyond the</p> <p>17 scope of conversations that I've had --</p> <p>18 Q. How many of these individuals were there</p> <p>19 who came to you with these questions?</p> <p>20 A. At least three or four people that I</p> <p>21 know.</p> <p>22 Q. And some were family and some were</p> <p>23 friends?</p> <p>24 A. Yes.</p> <p>25 Q. And when they asked you, "Am I at risk,"</p>

<p style="text-align: right;">Page 38</p> <p>1 you did not ask them, "What is your dose of 2 medication," correct? 3 MR. VAUGHN: Objection, misstates prior 4 testimony. 5 A. That -- I did not do a risk assessment 6 for any individual. What I did was, people came and 7 asked me whether this is something they should worry 8 about, what did I think about the -- about these 9 particular impurities in the product. And my answer 10 is, they can increase their risk of cancer, they are 11 known genotoxins. I wouldn't be taking a drug with 12 those, if I -- if it was me, I would talk to your 13 doctor. 14 Q. Have you ever done a study that was 15 funded by Plaintiffs' lawyers? 16 A. I don't believe so. Other than the -- 17 by "study," you mean a test or a clinical study or an 18 animal study, I have not. No. 19 Q. Do you intend to publish any of your 20 theories related to this litigation in the 21 peer-reviewed literature? 22 A. I have not done so, and I don't right 23 now have a plan to do so. Typically I wouldn't do so 24 without understanding what limits or constraints 25 there may be in terms of confidentiality agreements</p>	<p style="text-align: right;">Page 40</p> <p>1 to divulge the specifics of a project without asking 2 a company to do that, if I could do that or not. 3 I assume you're limiting that to 4 regulatory consulting. You're not asking about the 5 litigation work, because that you could find, when 6 you -- if you look at my trial work. 7 Q. Have you ever done any litigation work 8 on behalf of a pharmaceutical manufacturer? 9 A. Yes. I did litigation work on behalf of 10 pharmaceutical manufacturers when I was working with 11 Environ between 1989 and 1997. They only worked for 12 industry in litigation. And there is a most recent 13 time would have been, probably about ten years ago, I 14 worked for a company, a Japanese company on an issue 15 that was being litigated. A Japanese drug company. 16 Q. What was the drug? 17 A. Oh, gosh, I don't remember the name off 18 the top of my head. A blood pressure medicine, but I 19 don't remember the name off the top of my head. 20 Q. Do you know if that blood pressure 21 medicine was ever found to have NDMA or NDEA? 22 A. Those were not the issues that I am 23 remembering from my work on the case, so I can't tell 24 you if it did. I just, that was not what we were 25 addressing or I was addressing.</p>
<p style="text-align: right;">Page 39</p> <p>1 that I've signed in terms of the documents I've 2 reviewed. 3 Q. Have you ever advised any pharmaceutical 4 companies on medications? 5 MR. VAUGHN: Object to form. 6 A. You need to be more specific by -- what 7 do you mean, "Advise pharmaceutical companies on 8 medications"? That's a really broad question. 9 Q. I'd like to know the names of all 10 medications for which you have provided consulting 11 services to pharmaceutical companies. 12 MR. VAUGHN: Doctor, to the extent that 13 you are not under a confidentiality agreement, you 14 may answer the question. 15 A. So most of the work that I do, have done 16 over the years with companies is considered 17 confidential. I don't even share names. Companies 18 typically that I'm currently working for, because 19 that's part of my business terms and part of the 20 agreements that I'm asked to enter into by companies. 21 I have testified before that in my, over 22 my 30-plus years experience, I have worked on 23 projects related to many of the largest drug 24 companies around, and many small companies as well. 25 But I don't feel that it's something that I could do</p>	<p style="text-align: right;">Page 41</p> <p>1 Q. Did you advise that company about the 2 potential risk in development of NDMA or NDEA in 3 blood pressure medication? 4 A. Already said it was not the issue of the 5 case. There were no issues about nitrosamines or 6 NDMA or NDEA in that particular case. 7 Q. I understand that. I'm just asking if 8 you happened to mention that issue to the company. 9 MR. VAUGHN: Objection, asked and 10 answered. 11 A. No, it was ten years ago. I don't think 12 I would have, no. 13 Q. And in the last ten years, have you done 14 any litigation work on behalf of a Defendant 15 pharmaceutical company? 16 A. Defendants, yeah. For pharmaceutical 17 companies, no. Not in litigation. I have consulted 18 with companies, but not litigation. 19 Q. Do you know of any medications besides 20 Valsartan that have had issues with NDMA or NDEA? 21 MR. VAUGHN: Object to form. 22 A. There certainly is -- have been -- have 23 been drugs mentioned on the FDA website and the trade 24 press, yes. 25 Q. Which other --</p>

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<p style="text-align: right;">Page 42</p> <p>1 A. Other sartans. Losartan I think is one, 2 Metformin is one I've seen, I don't know. To get the 3 complete risk, I'd refer you to the FDA site. 4 Q. Understood. I'm just asking which ones 5 you know about. 6 A. Off the top of my head, those are ones 7 that I can recall. 8 Q. Just the sartans and Metformin? 9 A. Yes. There's others. I just don't 10 remember the names off the top of my head. 11 Q. Are you serving as an expert in any 12 other nitrosamine litigation right now? 13 A. No. 14 Q. Have you ever served as an expert in any 15 other nitrosamine litigation? 16 A. No, I have not. 17 Q. When did you first form the opinion that 18 Valsartan that contained NDMA and/or NDEA impurities 19 was adulterated? 20 MR. VAUGHN: Object to foundation. 21 A. The opinions that I've expressed in my 22 report, where I talk about the products that would be 23 deemed adulterated, would have been developed at the 24 time I wrote the report so then before the date of 25 the report, October 31st, would have been sometime</p>	<p style="text-align: right;">Page 44</p> <p>1 that's what I mean by that. I mean that -- if the 2 facts and evidence in this case show that at least at 3 the time that Novartis identified -- I described this 4 in my report in 2018 to ZHP -- the presence where 5 they had found it, the presence when it's found 6 indicates that it's adulterated because it is not 7 something that was meant to be there, and it is a 8 potent genotoxin, and that's been known from well 9 before that time period. 10 In this particular case, there's also 11 facts and evidence to indicate that as early as the 12 2014 time frame, the company, being ZHP, was making 13 product where there were unidentified peaks that they 14 were not pursuing. So the presence of those 15 impurities, the fact that for a time raises questions 16 about the quality of the product, even though they 17 had not identified those particular ones at that 18 particular time as being, for example, NDMA. 19 However, if they had done, if the 20 company had done the proper risk assessment, chemical 21 process assessment at the time that they changed from 22 the TIN process to the other process they were using, 23 I believe, it's my opinion that the risk assessment 24 would have gone led to, potentially, some knowledge 25 about this issue and that I think is also the opinion</p>
<p style="text-align: right;">Page 43</p> <p>1 earlier in 2022. I can't give you an exact date. 2 And I would state that the -- and those opinions were 3 developed based on a review of findings of FDA along 4 those lines, where they actually sent a warning 5 letter related to that. 6 Q. When did the FDA send a warning 7 letter -- when did the FDA first send a warning 8 letter with the word "adulterated" in it? 9 MR. VAUGHN: Object to form. 10 A. I want to say that there's a warning 11 letter that I'm aware of in 2019. I don't know if 12 there were other warning letters that existed. I 13 don't know and the one I'm thinking about is one that 14 went to ZHP. 15 Q. Do you hold the opinion that Valsartan 16 was adulterated before that -- before 2019? 17 A. It's my opinion that it would have been 18 deemed adulterated based on what was -- what the 19 evidence in the case appears to show, yes. 20 Q. What -- 21 A. Based on -- 22 Q. -- I didn't mean to interrupt you. So 23 sorry. 24 A. No, go ahead and follow up, because I 25 think you were going to ask it of me, right? If</p>	<p style="text-align: right;">Page 45</p> <p>1 of Dr. Hecht and others in this case. He addresses 2 that more directly than I do. 3 I happen to rely on what I see described 4 in the documents and facts as they present it, and I 5 describe in my report. 6 Q. What specific things should ZHP have 7 done in its risk assessment that it didn't do, like 8 what specific tasks? 9 MR. VAUGHN: Object to form. 10 A. I don't think I could -- I don't think I 11 have laid out a set of specific tasks in my report, 12 but I would tell you that in my report, as I 13 describe, the risk assessment process is 14 understanding breakdown byproducts, degradation 15 products that could occur and with -- as Dr. Hecht 16 has explained, I'd refer you to him to talk about the 17 details of the process and what it was that, from the 18 chemist's point of view, was so critical. 19 But certainly, from the what the 20 evidence in this case shows, the company themselves 21 understood that they weren't looking at a full 22 evaluation. That's what needs to be done. If you 23 don't do a full evaluation, then you never know. 24 Q. Is it your opinion that any risk 25 assessment that did not identify NDMA would have been</p>

<p style="text-align: right;">Page 46</p> <p>1 inadequate?</p> <p>2 A. I don't think I said that, no. I think</p> <p>3 what I said is, by not conducting an adequate risk</p> <p>4 assessment or a full risk assessment of their</p> <p>5 chemical process, that they have put patient health</p> <p>6 at risk because of their lack of understanding of</p> <p>7 what could occur and what impurities are in it now.</p> <p>8 Q. What didn't they do, like what should</p> <p>9 they have done more that would have made it adequate,</p> <p>10 like what actual things?</p> <p>11 MR. VAUGHN: Object to form.</p> <p>12 A. I think I've already tried to answer</p> <p>13 that. I said it's my opinion they should have</p> <p>14 understood the potential for the different changes in</p> <p>15 their process where they went from a TIN process to</p> <p>16 the other, to introduce the nitrosamines, based upon</p> <p>17 doing a chemical process review. However, Dr. Hecht</p> <p>18 and the chemists in the case are the ones to talk to</p> <p>19 if you want to understand the chemistry and what was</p> <p>20 so important about this step or that step.</p> <p>21 If you're asking me about a step in</p> <p>22 terms of a process they could have used, it's just</p> <p>23 understanding every input and every output and what</p> <p>24 are potential chemical reactions that could occur.</p> <p>25 Q. You are offering an opinion that the</p>	<p style="text-align: right;">Page 48</p> <p>1 Instead, what the guidance says is, you</p> <p>2 must understand, and understand the risks and look at</p> <p>3 your chemical process to identify things such as</p> <p>4 potential degradation products, potential byproducts.</p> <p>5 The fact that the company stipulates, the company</p> <p>6 being ZHP in this case, stipulates that they didn't</p> <p>7 do that, that's important to my opinion.</p> <p>8 It's also important in this case, that</p> <p>9 companies like Teva/Torrent, and I describe this in</p> <p>10 my report as well, don't appear to have known what</p> <p>11 they should have done in terms of checking on what</p> <p>12 the ZHP was indeed telling them that they did or</p> <p>13 didn't do.</p> <p>14 So regardless of whether or not ZHP has</p> <p>15 a duty, Torrent/Teva also have duties to make sure</p> <p>16 that they have validated their API suppliers, and</p> <p>17 understand that their API supplier is doing all the</p> <p>18 things they need to do in order to produce a quality</p> <p>19 product.</p> <p>20 Q. Is it your opinion, every drug that</p> <p>21 contains an impurity is adulterated?</p> <p>22 MR. VAUGHN: Object to form.</p> <p>23 A. Depends. I can't say yes or no. It</p> <p>24 depends. It depends on the situation. So there are</p> <p>25 certain types of impurities that are allowed based</p>
<p style="text-align: right;">Page 47</p> <p>1 risk assessment was not adequate, so I'm trying to</p> <p>2 understand what other things you believe, criticize</p> <p>3 Dr. Hecht, what you believe ZHP should have done to</p> <p>4 have an at quality risk assessment?</p> <p>5 A. I think my opinion has been that the</p> <p>6 risk assessment wasn't adequate. It's based first on</p> <p>7 admissions by the company, when they say they didn't</p> <p>8 do a full review of their chemical process. That</p> <p>9 right there indicates to me that the risk assessment</p> <p>10 was not adequate. They are stipulating to that.</p> <p>11 Because part of that exchange, when you change a</p> <p>12 chemical process based upon the guidance from FDA and</p> <p>13 what in my experience companies do when they make a</p> <p>14 change to a chemical process, that they look at those</p> <p>15 potential reaction pathways.</p> <p>16 I'm not an organic chemist by expertise.</p> <p>17 I have training in organic chemistry but I</p> <p>18 particularly am not doing organic chemistry in this</p> <p>19 case. That's the person that can describe for you</p> <p>20 the details in terms of how they should have looked</p> <p>21 at each of the inputs. It's not that there's a</p> <p>22 prescribed set of things people do, it's not like I</p> <p>23 can say to you that, "Go to this particular document</p> <p>24 and it will lay out from a regulatory perspective ten</p> <p>25 steps that must be done."</p>	<p style="text-align: right;">Page 49</p> <p>1 upon the USP compendium. There are ones that have</p> <p>2 been identified and ones that are post-identification</p> <p>3 or accepted to be present in a product, and those</p> <p>4 evaluations are, you know -- know what those are.</p> <p>5 Right? We know what it is, impurity A, impurity B,</p> <p>6 impurity C, we see that occurring based upon the</p> <p>7 evaluation of regulatory agencies. Those are allowed</p> <p>8 or, based on the development of the product, and in</p> <p>9 the monogram, those are allowed.</p> <p>10 But it just depends. If this is a new</p> <p>11 impurity, and an unknown impurity, something that the</p> <p>12 company gets because it's -- they have changed the</p> <p>13 process, then in those cases I would argue that you</p> <p>14 won't go -- those are the present impurities that</p> <p>15 could very well make it adulterated, but you have to</p> <p>16 figure it out. You have to know it's there to</p> <p>17 classify whether or not it is a genotoxin, for</p> <p>18 example.</p> <p>19 Q. Can generic drug contain an</p> <p>20 impurity that's not contained in the RLD? And I</p> <p>21 think we can agree what the term "RLD" means,</p> <p>22 correct?</p> <p>23 A. Reference Listed Drug, yes.</p> <p>24 Q. If a generic drug contains an impurity</p> <p>25 that's not present in the RLD, is that generic drug</p>

<p style="text-align: right;">Page 50</p> <p>1 adulterated?</p> <p>2 A. Depends, same thing. Depends upon what</p> <p>3 it is, and what work that the company -- at the</p> <p>4 companies that are making the generic drug did in</p> <p>5 order to identify and understand their process. So</p> <p>6 it could be, yes.</p> <p>7 Q. Is there an objective standard to know</p> <p>8 when a generic drug that contains an impurity not</p> <p>9 present in RLD is adulterated?</p> <p>10 MR. VAUGHN: Object to form.</p> <p>11 A. I don't think I understand your</p> <p>12 question, because are you asking me --</p> <p>13 Q. Well, like you said it depends, so I'm</p> <p>14 trying to understand, is there like an objective</p> <p>15 standard that I can apply to know when a generic drug</p> <p>16 has an impurity, it's not in the RLD, what's the</p> <p>17 standard to determine whether it's adulterated in</p> <p>18 your opinion or not?</p> <p>19 A. The standard of what is, is -- standard</p> <p>20 is what it is. For example, is it a genotoxin or</p> <p>21 not, is it a potent toxin or not? Understanding what</p> <p>22 the impurity is.</p> <p>23 Are you asking me is there some level of</p> <p>24 impurity that -- well, USP monographs indicate</p> <p>25 potentially? Yes, some monographs will say that this</p>	<p style="text-align: right;">Page 52</p> <p>1 understand your processes and what can potentially be</p> <p>2 produced.</p> <p>3 Q. What is the difference between a</p> <p>4 genotoxin and a potent genotoxin? You've used both</p> <p>5 terms and I want to make sure I understand how you're</p> <p>6 differentiating them.</p> <p>7 A. So "genotoxin" just means generally that</p> <p>8 the product, the chemical or the compound, or</p> <p>9 impurity, has the potential to damage or affect gene</p> <p>10 expression or cause mutations. There's a variety of</p> <p>11 types of endpoints. Genotoxicity just means that</p> <p>12 something produces an adverse effect through a</p> <p>13 mechanism related to DNA damage of some type.</p> <p>14 A potent genotoxin, the reason I'm using</p> <p>15 it here, is because these compounds are that. These</p> <p>16 are ones that are known to be some of the most potent</p> <p>17 in terms of the propensity to, or their ability to</p> <p>18 product DNA damage.</p> <p>19 Q. And is there literature that references</p> <p>20 to NDMA as a potent genotoxin? Where can I find that</p> <p>21 term in the literature?</p> <p>22 A. I don't know if I cited that term. Let</p> <p>23 me see if I cited that in my report, to use that.</p> <p>24 MS. MILLER: While you're looking, let's</p> <p>25 just mark Dr. Plunkett's report as Exhibit 1.</p>
<p style="text-align: right;">Page 51</p> <p>1 impurity at this level is allowable. Is that what</p> <p>2 you're asking me? I can't tell you any particular</p> <p>3 one but you can go to the monogram for different</p> <p>4 drugs and they do list that.</p> <p>5 Q. Are you talking about the USP monograph?</p> <p>6 At the time that these products were on the market,</p> <p>7 impurities under .1 did not have to be identified, is</p> <p>8 that correct?</p> <p>9 MR. VAUGHN: Object to form.</p> <p>10 A. As long as they are -- as long there was</p> <p>11 an understanding that they were not potent toxicants,</p> <p>12 or potent genotoxicants, yes, that is a standard that</p> <p>13 could have been applied, depending upon your process.</p> <p>14 But again, this comes back to whether or</p> <p>15 not what you're doing is the process that's in the</p> <p>16 monograph. So when you change that process, which is</p> <p>17 what happened here, the RLD process was the TIN</p> <p>18 process, right? That's the one that Diovan, the RLD,</p> <p>19 was produced under, and that's what the monograph was</p> <p>20 set around.</p> <p>21 In this particular case, the companies</p> <p>22 are using a different process to produce their</p> <p>23 product so just pointing back to the monograph and</p> <p>24 saying, "That is adequate," isn't adequate unless you</p> <p>25 know it's adequate, which means you need to</p>	<p style="text-align: right;">Page 53</p> <p>1 EXH (Plunkett Exhibit 1, expert report of</p> <p>2 Laura M. Plunkett, Ph.D., DABT, dated 10/31/22,</p> <p>3 marked for identification, as of this date.)</p> <p>4 (A pause in the proceedings.)</p> <p>5 A. So my paragraph 43 is where I call them</p> <p>6 potent carcinogens. So potent carcinogens, I would</p> <p>7 argue, could also apply to potent genotoxins as well,</p> <p>8 could also be a potent genotoxin because we know</p> <p>9 that's the mechanism by which these compounds appear</p> <p>10 to act to produce cancer.</p> <p>11 It's my statement and I think it's</p> <p>12 consistent with my review of the literature, so</p> <p>13 that's about the only thing I could answer for you</p> <p>14 right now based upon my report.</p> <p>15 Q. You can't actually point to any</p> <p>16 literature that uses the word "potent genotoxin" with</p> <p>17 respect with respect to either NDMA or NDEA?</p> <p>18 A. I know I've seen it before but I'd have</p> <p>19 to go back and find it because I don't cite to that</p> <p>20 in my report. So I can't answer that without going</p> <p>21 back and looking at my library of textbooks and other</p> <p>22 types of monographs and information. I believe you</p> <p>23 might see that described that way within either the</p> <p>24 IARC document, or within the WHO or the NCP or EPA</p> <p>25 documents that talk about the -- to find it, that I'd</p>

<p style="text-align: right;">Page 54</p> <p>1 have to go look for you. I would argue that I don't 2 believe there's any controversy that most 3 toxicologists would call them potent genotoxins based 4 on any data that exists. 5 Q. I can tell you that I've not seen that 6 term -- 7 MR. VAUGHN: Object, argumentative. 8 Q. -- I'm wondering if you have actually 9 seen that term anywhere in the literature. 10 A. I believe I have. But again, regardless 11 of whether I have or not, as a toxicologist, the 12 behavior of NDMA and NDEA in particular, in animal 13 studies, for example, and also in in vitro studies 14 for genotoxicity indicate that it's a potent compound 15 to produce the effects that it does. 16 And so I'm calling it either a potent 17 carcinogen, I would call it potent toxicant, I would 18 also call it a potent genotoxin because it is one 19 that reliably, over and over again, in fact, with the 20 animal studies, what's interesting as I described in 21 paragraph 43, there's actually a study showing that 22 single doses prenatally have been shown to be 23 carcinogenic in animals once they are born, a pretty 24 potent effect. 25 Q. Can you give me an example of a</p>	<p style="text-align: right;">Page 56</p> <p>1 million or one in a hundred thousand risk level. You 2 can do that based on animal data. 3 Q. Are NDMA and NDEA found in foods? 4 A. Are you asking me are they found in any 5 food at all? They can be. Depends on the conditions 6 under which the, for example, maybe the food is 7 cooked, that has some effect on that but there is in 8 background level of exposure, yes. 9 Q. Have those foods been banned by the FDA? 10 MR. VAUGHN: Object to form. 11 A. That's beyond the scope of the work that 12 I did, to look to see if that's true for any -- so I 13 would say to you, I don't have an opinion one way or 14 the other. I'm not aware of some of those foods 15 being banned, no, I'm not aware of that. But it's a 16 very different thing to talk about something that can 17 be controlled and something that can't be controlled. 18 So talking about exposures in food that may be there 19 and are things that it's very difficult to control, 20 whereas we know that this drug can be made without 21 it. 22 So there's a different calculus when you 23 talk about looking at risks posed by food versus risk 24 posed by a drug where we know you can make it without 25 them there.</p>
<p style="text-align: right;">Page 55</p> <p>1 genotoxin that's not potent? 2 A. Lead is an example of something that's 3 not a potent genotoxin. It has genotoxicity effects 4 in some assays but not in all. "Potent" in 5 genotoxicity, typically as a toxicologist, I would 6 use that word because regardless of the assay you 7 test it in and how many times you test it over and 8 over again, it produces genotoxic effect across the 9 range of exposure levels in cells with and without 10 activation. 11 Q. Do you have an opinion as to what dose 12 of NDMA or NDEA is necessary to render those -- to 13 render them carcinogenic? 14 MR. VAUGHN: Object to form. 15 A. That's beyond the scope of what I did. 16 I told you that earlier. However, there are others 17 who have addressed that. And in this litigation, and 18 I would also say there are potentially, you can go 19 back and look at the IARC monograph where it goes 20 through all the studies and exposure levels and what 21 the extrapolated cancer risk would be based on 22 different exposure levels in animal studies. So that 23 you can get to. 24 You can get to where this -- what 25 exposure level increases cancer above the one in a</p>	<p style="text-align: right;">Page 57</p> <p>1 Q. If a family member had come to you and 2 said, "I just found out there's NDMA in one of the 3 foods I like, herring, I like herring and there's 4 NDMA in herring," would you have told them to stop 5 eating herring? 6 MR. VAUGHN: Object to form. 7 A. I don't think I would have. I would 8 have told them that I'd have to do an investigation 9 because it really depends on what people are eating, 10 how their foods are prepared, those are all important 11 for potency of that. Foods can have things in them 12 that are harmful, but typically the things that foods 13 have in them that are harmful are not at the levels 14 that we're talking about in this case, for this 15 particular impurities. That could have occurred at 16 many, many orders of magnitude higher than the levels 17 that may be found in food. 18 Q. Have you told any members of your family 19 or any friends to stop eating cured meats because 20 they contain nitrosamines? 21 A. No, I've never been asked that. 22 Q. Have you told any members of your family 23 or any friends to stop eating bacon because it 24 contains nitrosamines? 25 MR. VAUGHN: Objection, foundation.</p>

<p style="text-align: right;">Page 58</p> <p>1 A. No. I've told people that they can be 2 harmful in terms of heart disease issues. People 3 have asked me that before. So for example, myself, I 4 try to eat less red meat but it just has to do with, 5 I'm in my 60s, I don't know, I'd like to remain 6 healthier as I go forward. 7 Q. Have you ever suggested to any family or 8 friends that they stop eating any fermented foods 9 because they contain nitrosamines? 10 MR. VAUGHN: Objection, foundation. 11 A. No one has ever asked me that question. 12 So -- 13 Q. Have you ever offered, unsolicited, sua 14 sponte, suggested to any of your loved ones to stop 15 having cured meat or bacon, or fermented foods 16 because of the nitrosamine content? 17 MR. VAUGHN: Objection, foundation. 18 A. Not solely based on that, no, as I 19 already answered. Typically the issue is whether or 20 not certain kinds of foods that you're talking about, 21 like cured meats, things like that, my issue is, as I 22 do believe that it's the higher -- meat generally is 23 better for you to some extent, but that's just 24 because of me and I have family risk factors for high 25 cholesterol levels and things like that.</p>	<p style="text-align: right;">Page 60</p> <p>1 exposure producing cytotoxicity before you get a 2 cancer or a genotoxic effect. 3 Those are kind of the kinds of 4 assessments that you can do in order to use 5 adjectives like "potent" or "not potent" when you're 6 talking about a compound. 7 Q. Fair enough, so let's just focus on 8 NDMA. Is the NDMA that's found in cured meat a 9 potent genotoxin? 10 MR. VAUGHN: Objection, foundation. 11 A. NDMA is a potent genotoxin by itself. 12 That's the opinion that I have. So regardless of 13 where you find it, it's a potent genotoxin. However, 14 like anything else that you talk about, you have to 15 consider whether or not, when you have a situation 16 where you can't control for it, or you can control 17 for it, that weighs into your calculation over how 18 you would handle and respond to the situation. 19 So in this case, we know we can make the 20 compound without the NDMA. That's really important. 21 And that's why in this particular case, I have formed 22 the opinions I have related to the responsibility of 23 the company, what should or shouldn't be done. This 24 thing can be made without it, it should be made 25 without it. It is not meant to be there.</p>
<p style="text-align: right;">Page 59</p> <p>1 So it's -- it's more complex than just 2 talking about -- and no one has ever asked me that 3 question so I haven't -- 4 Q. Are the nitrosamines in cured meat, 5 bacon, and fermented foods potent genotoxins? 6 MR. VAUGHN: Objection, foundation. 7 A. Well, I'm not sure which ones you're 8 referring to, because there's a variety of 9 nitrosamines. Some are more potent than others. So 10 NDMA and NDEA are some of the more potent ones. So 11 the issue, this is the issue for food. 12 So food can have many different 13 N-nitroso compounds potentially in them, some of 14 which actually have been shown to carry a different 15 level of risk than others. And at issue in this 16 case, these particular ones, NDMA and NDEA, are ones 17 that are labeled as probably human carcinogens, 18 specifically because the data has been so consistent 19 showing that they are indeed able to, or have been 20 associated with, I guess, in the animal studies, 21 cancer repeatedly over and over again. 22 There is a mechanism that has been 23 linked to genotoxicity. And again, the exposure 24 levels have been across the exposure levels. It's 25 not like you have to have a very high level of</p>	<p style="text-align: right;">Page 61</p> <p>1 Q. Is cured meat containing NDMA a potent 2 genotoxin? 3 A. It's not the cured meat. I already 4 answered this question. You talk about what a 5 compound is and then from there, you have to do an 6 assessment of where it is, how it got there, should 7 it be there, can it be controlled or not. 8 I'm not arguing with you, but I'm aware 9 that nitrosamines can occur in food. I've already 10 answered that question. It can. But there's an 11 important contextual discussion that's different for 12 the risk in food versus the risk in these products, 13 and so I would argue to you, based on my experience 14 and training, that when you have a compound like 15 this, a potent genotoxin in a drug product and you 16 can make that drug without it, just as FDA has said, 17 you should be making it without it. You should 18 prevent it or remove it. It's unacceptable for it to 19 be there. 20 And that's a different assessment than 21 you would do if you were talking and considering 22 issues related to food safety. 23 Q. Is cured meat with NDMA carcinogenic? 24 A. It's the same answer. I wouldn't answer 25 that cured meat is carcinogenic, I would tell you</p>

<p style="text-align: right;">Page 62</p> <p>1 that NDMA is carcinogenic and as a result of that, 2 you would look at the safety of the food as it would 3 or wouldn't exist related to the presence of things 4 such as nitrosamines in it. And it really -- it's -- 5 I'm not trying to be a maven, I'm just telling you 6 it's different -- you're talking apples and oranges 7 when you talk about food safety assessment versus 8 prescription drug assessment for presence of an 9 impurity.</p> <p>10 Q. Do you believe that cured meat with NDMA 11 should be banned?</p> <p>12 A. I have -- that's beyond the scope of any 13 opinion. I haven't formed that opinion, no.</p> <p>14 Q. How about smoked and salted fish that 15 contains NDMA, do you think it should be banned?</p> <p>16 MR. VAUGHN: Objection, foundation, 17 scope, relevancy.</p> <p>18 A. I have not formed opinions about banning 19 any particular food that would or wouldn't contain 20 any nitrosamines at this point in time.</p> <p>21 Q. Would you advise a family member or 22 friend to stop eating smoked salmon if that smoked 23 salmon contains NDMA?</p> <p>24 MR. VAUGHN: Objection, relevance.</p> <p>25 A. I don't know. It depends upon the</p>	<p style="text-align: right;">Page 64</p> <p>1 you're asking me, I think, that's the only thing that 2 makes sense -- a population of people that are eating 3 salted fish or smoked fish. And we know that there 4 are certain kinds of background levels and certain 5 kinds of compounds that are in those particular 6 products. Is there a level at which it could be 7 adjusted and said to be safe? I have not done those 8 assessments. And I think it would be highly 9 dependent upon a lot of things. What particular 10 nitrosamines you're detecting, how many of them, 11 whether or not they occur at all times, whether it's 12 something that could be also controlled by the way 13 you smoke the meat, for example, or smoke the fish. 14 Those are all relevant to that.</p> <p>15 I'm not aware of any -- of FDA banning, 16 for example, smoked fish. I'm not aware of those 17 kind of things happening, for those kind of products. 18 But that doesn't mean, like anything else, that you 19 can't go to the FDA website, which I know you can, 20 where they have discussions of nitrosamines in food. 21 So you can see that there are discussions about 22 certain kinds of foods having higher levels than 23 others in those kinds of things.</p> <p>24 Q. Does your level of exposure to NDMA 25 affect whether it increases your risk of cancer?</p>
<p style="text-align: right;">Page 63</p> <p>1 situation what you're talking about. What 2 nitrosamines -- what -- what are you talking about? 3 Was it something that has -- that can't be controlled 4 for, they eat it once a week, they eat it every day? 5 I mean, there's all kinds of things.</p> <p>6 Again, food safety assessment is 7 different than what we're doing here. I have not 8 done those assessments and I have not advised anyone 9 based upon that other than generally, like I told 10 you, that I think red meat can be a problem for heart 11 disease, so I choose to eat less of that.</p> <p>12 Q. We we're talking about fish right now, 13 not red meat, right?</p> <p>14 MR. VAUGHN: Objection, argumentative.</p> <p>15 Q. My example was smoked salmon. So my 16 question for you is, you said it depends if they eat 17 it once a week or not. Is that because the dose of a 18 carcinogen is relevant to safety?</p> <p>19 MR. VAUGHN: Object to form.</p> <p>20 A. For food safety, it's not the dose, it's 21 exposure level. So the exposure level is relevant to 22 food safety assessment. It's understanding what are 23 the ranges of a -- what is the range of levels that 24 could or couldn't occur in food, but you do look at, 25 you make for a population assessment -- which is what</p>	<p style="text-align: right;">Page 65</p> <p>1 A. As a regulatory consultant, I am not 2 making an -- the opinion of a specific increased risk 3 level, no. So in my report based on my role in this 4 litigation, no, I have not formed that opinion, it 5 has to be at a certain level or not. What my opinion 6 is, as I've already told you, is that it's an 7 impurity that is not acceptable, not supposed to be 8 there, so any NDMA makes this product unacceptable 9 and increases your risk.</p> <p>10 Q. At the beginning of your deposition you 11 said you were here both as a toxicologist and as a 12 regulatory expert. I'm asking this question as a 13 toxicologist. My question as a toxicologist is, does 14 the level which you're exposed to NDMA affect whether 15 or not it increases your risk of cancer?</p> <p>16 MR. VAUGHN: Objection, scope.</p> <p>17 A. It's beyond what I was asked to do in 18 this case. So from a general -- from a general 19 discussion of toxicology, I've already described for 20 you that in the terms of cancer risk assessment for 21 these kinds of compounds, the assumption is that 22 there is no safe level. In other words -- and then 23 what you have to do instead is balance what you 24 assume was exposure would be and talk about what is* 25 that increased cancer risk level, are you willing to</p>

<p style="text-align: right;">Page 66</p> <p>1 accept one cancer in a million or one in a hundred 2 thousand or one in ten thousand, and those are 3 decisions that are made by regulatory bodies or 4 scientists in order to describe the risk. 5 But that's why cancer is not described 6 as an ADI. It's not like you can go and say, "This 7 level of exposure, if you're exposed to this level 8 there is absolutely no risk." That doesn't exist for 9 these kinds of compounds. 10 Q. Based on a safe level exposure to NDMA, 11 would that apply to foods as well as medications? 12 MR. VAUGHN: Objection, scope. 13 A. The issue of -- the issue of NDMA 14 generally, and doing a risk assessment would be that 15 there is an understanding that there -- that 16 cancer -- cancer risk and safety assessment is done 17 differently than it is for a non-cancer event. 18 As a result, if you're going to do a 19 food safety assessment, if you're going to do a drug 20 safety assessment in this case, or a risk assessment, 21 you have to somehow go through the process of 22 determining how -- what level of risk is acceptable 23 to you as a regulator. And that's what the regulator 24 would do, or you as a toxicologist. 25 It was beyond the scope of what I did to</p>	<p style="text-align: right;">Page 68</p> <p>1 use as toxicologists to look at cancer risk. That 2 methodology, it is premised only the basis of what is 3 the risk that would be acceptable or not acceptable. 4 So you would set an exposure level which you're 5 willing to live with, based upon whether you are okay 6 with one in ten thousand, one in a hundred thousand, 7 one in a million increase in cancer risk. 8 However, on -- that's for population. 9 For any one individual, the answer could be very 10 different. And that's because each individual you 11 might look at might have other susceptibilities, 12 other types of risk factors that would tell you that 13 you would want to have a different paradigm or a 14 different metric for determining whether or not it's 15 likely that cancer would develop because, don't 16 forget, that's a lot of what we're doing here. 17 And what I was explaining to you is, to 18 try to give you an understanding, it's very different 19 than the way we look at non-cancer risk assessment, 20 where we can identify or we assume we can identify a 21 level with no risk. 22 MS. MILLER: Let's take a break. 23 VIDEOGRAPHER: Going off the record. 24 The time is 10:49 a.m. This is the end of media unit 25 1.</p>
<p style="text-align: right;">Page 67</p> <p>1 do any specific assessments for any specific 2 individuals in this particular case based on any 3 particular exposure pattern. 4 Instead, what I'm telling you as a 5 toxicologist is, maybe the best way to describe it 6 is, there's two ways toxicology can describe cancer. 7 It can describe it based on whether or not generally 8 it poses a hazard of cancer. If there's an increased 9 risk, does it exist or not? 10 Yes, I'm saying it does exist, and then 11 after that, in order to qualify the risk, you as a 12 toxicologist could look for the specific set of 13 facts. That was beyond the scope of what I did but 14 there are others in this litigation who are doing 15 that. 16 Q. I don't really think that answered my 17 question. It was actually much simpler. My simple 18 question was, you said there's no safe level of 19 exposure to NDMA in medication. Is there a safe 20 level of exposure to NDMA in food? 21 MR. VAUGHN: Objection -- 22 A. I don't think that is what I said. I'd 23 have to go back and look at the record to see what 24 you're saying I said. What I'm saying to you is, 25 NDMA is carcinogenic based upon the methods that we</p>	<p style="text-align: right;">Page 69</p> <p>1 (Recess taken.) 2 VIDEOGRAPHER: We're back on the record. 3 The time is 11:08 a.m. This is the beginning of 4 media unit 2. 5 MS. MILLER: Thank you. I'm going to 6 mark as Exhibit 2 a July 13, 2018 FDA press release. 7 EXH (Plunkett Exhibit 2, FDA press release 8 dated 7/13/18, marked for identification, as of this 9 date.) 10 THE WITNESS: Are you putting these in 11 the Exhibit Share file or -- because I know that if I 12 need to look at more than you put on the screen I can 13 do that? 14 MS. MILLER: I think we can give you 15 control, right? 16 MR. VAUGHN: As the defending attorney, 17 I need to be able to view the full exhibit. 18 THE WITNESS: So you're putting it in 19 the share? 20 MS. MILLER: We're doing both. We're 21 putting it on the screen and at the same time Alex is 22 putting it into whatever the appropriate protocol is. 23 EXAMINATION (Cont'd.) 24 BY MS. MILLER: 25 Q. Dr. Plunkett, are you familiar with this</p>

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<p style="text-align: right;">Page 70</p> <p>1 press release?</p> <p>2 A. Yes, it's been a while since I've looked</p> <p>3 at this one but yes, I am familiar with it.</p> <p>4 Q. If we can look at the bottom sentence on</p> <p>5 the screen, it says the presence of NDMA was</p> <p>6 unexpected, do you see that?</p> <p>7 A. I do.</p> <p>8 Q. Do you agree with the FDA that the</p> <p>9 presence of NDMA was unexpected?</p> <p>10 A. If by "unexpected," you were defining</p> <p>11 that as something that was not part of the monograph</p> <p>12 for the drug and also was something that they had not</p> <p>13 seen before, that unexpected I would agree with. But</p> <p>14 I don't believe if you're going to use the -- a</p> <p>15 definition that it couldn't have been known, I</p> <p>16 disagree with that.</p> <p>17 Q. Do you know what the FDA meant when it</p> <p>18 said the presence of NDMA was unexpected?</p> <p>19 A. I can only read that based upon the</p> <p>20 general English understanding of "unexpected" --</p> <p>21 Q. And what is the general English</p> <p>22 understanding of the the word "unexpected"?</p> <p>23 A. Something -- I would say something that</p> <p>24 you had not seen before.</p> <p>25 Q. Is that a dictionary definition of</p>	<p style="text-align: right;">Page 72</p> <p>1 "unexpected" here is used in a regulatory context</p> <p>2 rather than in the general understanding of the word</p> <p>3 "unexpected"? That's my question.</p> <p>4 MR. VAUGHN: Object to form.</p> <p>5 A. I would say, since this was written by a</p> <p>6 regulatory agency, that they are calling it as a</p> <p>7 general English meaning of "unexpected" because this</p> <p>8 is a press release, that for consumers to view as</p> <p>9 well, but also understanding that as a regulatory</p> <p>10 agency, they will choose their words based upon their</p> <p>11 role, their duty and their responsibility.</p> <p>12 Q. Let's move on to Exhibit 3. I'm marking</p> <p>13 as Exhibit 3, an August 30, 2018 FDA statement.</p> <p>14 EXH (Plunkett Exhibit 3, FDA statement dated</p> <p>15 8/30/18, marked for identification, as of this date.)</p> <p>16 MR. VAUGHN: Jessica, I'm not seeing the</p> <p>17 exhibits in the share folder.</p> <p>18 MS. MILLER: Alex is going to figure</p> <p>19 that out. Why don't we go off the record and figure</p> <p>20 out for a minute, just to figure out how to make this</p> <p>21 exhibit process more efficient.</p> <p>22 VIDEOGRAPHER: Okay, going off the</p> <p>23 record. The time is 11:14 a.m.</p> <p>24 (Discussion off the record.)</p> <p>25 VIDEOGRAPHER: We're back on the record.</p>
<p style="text-align: right;">Page 71</p> <p>1 "unexpected," something you had not seen before?</p> <p>2 A. I don't know.</p> <p>3 MR. VAUGHN: Object to form.</p> <p>4 A. I mean, there's multiple definitions,</p> <p>5 I'm sure in the general dictionary. As a regulatory</p> <p>6 expert, that's how I define the word "unexpected"</p> <p>7 based on the general imagery.</p> <p>8 Q. Is "unexpected" a regulatory term?</p> <p>9 A. Well, I've seen it used in regulatory --</p> <p>10 this is a regulatory document. It's something, FDA,</p> <p>11 the regulatory agency, was writing it, so that's how</p> <p>12 I am defining it based upon my experience.</p> <p>13 Q. And in your experience, does the term</p> <p>14 "unexpected" have a different meaning in the</p> <p>15 regulatory context from the regular speech casual way</p> <p>16 in which the term is used?</p> <p>17 MR. VAUGHN: Object to form.</p> <p>18 A. Highly dependent upon the speaker, in</p> <p>19 the context of a sentence and the information there.</p> <p>20 But in my view, "Unexpected" here is telling me that</p> <p>21 the presence of NDMA is something that they did not</p> <p>22 know was there, "They" being the FDA. It wasn't part</p> <p>23 of the monograph, it wasn't something that they had</p> <p>24 been told by somebody.</p> <p>25 Q. Is it your understanding that the word</p>	<p style="text-align: right;">Page 73</p> <p>1 The time is 11:20 a.m.</p> <p>2 EXAMINATION (Cont'd.)</p> <p>3 BY MS. MILLER:</p> <p>4 Q. I think we were at Exhibit 3, and Alex</p> <p>5 is putting it on the screen and it's an August 30th,</p> <p>6 2018 FDA statement. Oh, just a moment, just to go</p> <p>7 back to Exhibit 2, the July 13th, 2018 press release,</p> <p>8 do you recall, Dr. Plunkett, if you mentioned that</p> <p>9 press release and the statement about the presence of</p> <p>10 NDMA being unexpected in your report?</p> <p>11 A. Oh, the press release is the only -- I</p> <p>12 listed the entire, all of the FDA statements, all</p> <p>13 there. I don't know that I mentioned that</p> <p>14 specifically, so I can't -- I don't believe I did,</p> <p>15 probably.</p> <p>16 Q. Okay. Let's move on to this Exhibit 3.</p> <p>17 Exhibit 3 again, as I said, is the</p> <p>18 August 30th, 2018 statement. This is called an FDA</p> <p>19 statement, not a press release. Dr. Plunkett, do you</p> <p>20 recall if you quoted this document in your report?</p> <p>21 A. All my reliance material, I know I</p> <p>22 quoted the follow-up, which was an update, in 2019.</p> <p>23 But I don't know if this one is there. You want me</p> <p>24 to look? I can look real quick.</p> <p>25 Q. If you don't know, I don't want to take</p>

19 (Pages 70 - 73)

<p style="text-align: right;">Page 74</p> <p>1 the time for you to look.</p> <p>2 MR. VAUGHN: Dr. Plunkett, take time to</p> <p>3 scroll through the document, so you know if you</p> <p>4 actually quoted it or not.</p> <p>5 (A pause in the proceedings.)</p> <p>6 Q. If we could turn to page 3 of this</p> <p>7 document, if you could look at the third paragraph</p> <p>8 that begins, "In St. Louis"?</p> <p>9 A. Yes, could you make it a little bit</p> <p>10 bigger? Just a little bit bigger, not a lot maybe.</p> <p>11 There you go, sorry. Are you talking about the</p> <p>12 highlighted box --</p> <p>13 Q. No, I don't know why those are</p> <p>14 highlighted. Those were not done by us.</p> <p>15 A. Okay. So starting --</p> <p>16 MR. VAUGHN: Was that highlighted on the</p> <p>17 FDA's website?</p> <p>18 MS. MILLER: I don't think these are</p> <p>19 highlights.</p> <p>20 MR. VAUGHN: Were these boxes on the FDA</p> <p>21 website?</p> <p>22 MS. MILLER: This is how it printed. If</p> <p>23 you look, every time it's highlighted there's a</p> <p>24 hyperlink, Brett. We didn't manipulate the document</p> <p>25 in any way, if that is what you're asking.</p>	<p style="text-align: right;">Page 76</p> <p>1 that was unsurmountable --</p> <p>2 Q. Does FDA say NDMA's properties can make</p> <p>3 it difficult to find, or does it say NDMA's</p> <p>4 properties make it difficult to find?</p> <p>5 A. The text says, "NDMA's properties make</p> <p>6 it difficult to find."</p> <p>7 Q. Do you agree with that statement?</p> <p>8 A. I'm not a chemist so that would -- I</p> <p>9 would defer that to Dr. Hecht.</p> <p>10 Q. Do you know why NDMA's properties make</p> <p>11 it difficult to find?</p> <p>12 A. The same answer. It's my understanding</p> <p>13 others can answer these questions for you as</p> <p>14 chemists, and I'm not the chemist in the case so I</p> <p>15 would defer to Dr. Hecht.</p> <p>16 Q. Okay. And if we could continue, if FDA</p> <p>17 says, "CDER scientists have now developed" -- I'm</p> <p>18 sorry, let me begin at the beginning of the sentence,</p> <p>19 "To determine if" --</p> <p>20 A. Could you -- stop.</p> <p>21 MS. MILLER: -- stop moving it around.</p> <p>22 You're just making us dizzy.</p> <p>23 Q. It says, "To determine if Valsartan</p> <p>24 products do contain this impurity, CDER's scientists</p> <p>25 have now developed the gas chromatography mass</p>
<p style="text-align: right;">Page 75</p> <p>1 MR. VAUGHN: Okay.</p> <p>2 Q. Okay. So my question is, if you read</p> <p>3 the third paragraph it states, "In St. Louis, FDA</p> <p>4 maintains the most advanced pharmaceutical laboratory</p> <p>5 of any regulatory agency in the world. As soon as we</p> <p>6 were aware of the NDMA impurity in certain valsartan</p> <p>7 drugs, we began collecting samples of all valsartan</p> <p>8 API and products marketed in the U.S. At the same</p> <p>9 time, our scientists began developing a test to</p> <p>10 detect and and quantify NDMA in Valsartan API.</p> <p>11 NDMA's properties make it difficult to find."</p> <p>12 Do you see that?</p> <p>13 A. I see that text, yes.</p> <p>14 Q. So the FDA here is stating that it has</p> <p>15 one of the most, or almost most advanced</p> <p>16 pharmaceutical laboratory of any regulatory agency in</p> <p>17 the world, correct?</p> <p>18 A. That is what they claim, yes.</p> <p>19 Q. And they state that they had a challenge</p> <p>20 in developing a test of quantifying DMA, correct?</p> <p>21 MR. VAUGHN: Object to form.</p> <p>22 A. No, I don't think they had a challenge.</p> <p>23 I think they pointed out that NDMA itself has</p> <p>24 properties that can make it difficult to find, but</p> <p>25 didn't say that it was necessarily a huge challenge</p>	<p style="text-align: right;">Page 77</p> <p>1 spectrometry headspace testing method." Do you see</p> <p>2 that sentence?</p> <p>3 A. I see that sentence.</p> <p>4 Q. So the FDA had to develop a new test in</p> <p>5 order to determine whether the Valsartan products</p> <p>6 contained NDMA?</p> <p>7 MR. VAUGHN: Objection, form, scope.</p> <p>8 Foundation.</p> <p>9 A. So that's beyond the opinions that I</p> <p>10 have developed. Again, I know that this is talked</p> <p>11 about in the other reports by other experts in this</p> <p>12 case. They did state that they developed a method,</p> <p>13 yes. That I agree, that's stated in the sentence.</p> <p>14 It has nothing to do with, in my view, any kind of</p> <p>15 judgement about the difficulty or the -- or the fact</p> <p>16 that they often develop tests. I mean, FDA develops</p> <p>17 tests all the time, and --</p> <p>18 Q. Do you know why FDA had to develop a new</p> <p>19 test?</p> <p>20 MR. VAUGHN: Object to form.</p> <p>21 A. I can't get into FDA's mind to know</p> <p>22 that. I can't tell you. I wasn't there to have a</p> <p>23 discussion with any particular chemist on why they</p> <p>24 did it. I know that the overall issue in the case,</p> <p>25 why it was needed, was because there were these</p>

<p style="text-align: right;">Page 78</p> <p>1 impurities being found and they didn't understand the 2 extent of the problem. 3 Q. Do you know whether FDA had any prior 4 tests that would have identified NDMA? 5 A. That's beyond the scope of what I did. 6 I would defer you to the other experts in the case 7 that are handling this area. 8 Q. If we could move on to page 4, first 9 paragraph. "We believe that these risks are 10 introduced through a specific sequence of steps in 11 the manufacturing process, where certain chemical 12 reactions are needed to form the active ingredient." 13 Do you see that? 14 A. I see that, yes. 15 Q. And the next sentence says, "Before we 16 undertook this analysis, neither regulators nor 17 industry fully understood how NDMA could form during 18 this process," do you see this sentence? 19 A. I see that sentence. 20 Q. Did you fully understand in 2018 how 21 NDMA could form during the process through which 22 Valsartan was manufactured? 23 MR. VAUGHN: Object to form. 24 A. Well, that wasn't my job. That was the 25 job of the companies making the product, to fully</p>	<p style="text-align: right;">Page 80</p> <p>1 process, and whose responsibility it was. Again, 2 it's not FDA's responsibility to understand. It's 3 the company's responsibility to understand, and then 4 provide that information to the regulatory agency. 5 Q. I just was asking if you used this quote 6 in your report. 7 A. I started -- I usually start, like I 8 did, I start out I said, I didn't cite this but, and 9 then I gave you an explanation. So I do believe I 10 answered your question in the first part of my 11 answer. 12 Q. Turning now to page 5. In the middle of 13 paragraph 2, the FDA states, "Was not anticipated 14 that NDMA would occur at these levels in the 15 manufacturing of the Valsartan API." Do you see 16 that? 17 A. The sentence that started with, 18 "Because," that's where you are? 19 Q. Correct. 20 A. I see that clause, yes. 21 Q. Do you agree with the FDA that it was 22 not anticipated that NDMA would occur at these levels 23 in the manufacturing of the Valsartan API? 24 A. I haven't formed an opinion on that one 25 way or the other. That was beyond the scope of my</p>
<p style="text-align: right;">Page 79</p> <p>1 understand the chemical process. 2 Q. Do you disagree with FDA's statement 3 that neither regulators nor industry fully understood 4 how NDMA could form? 5 MR. VAUGHN: Object to form. 6 A. I neither agree nor disagree with that 7 statement. It is a statement, is what it is. But I 8 would point to the fact that it's the job of the 9 industry to fully understand their chemical processes 10 and the ways that potentially harmful compounds can 11 be formed during those processes, and this is what 12 the company has stipulated they did not do. 13 Q. Is it possible for a company to perform 14 an adequate risk assessment and still not identify 15 certain risks that are hard to find? 16 MR. VAUGHN: Object to form. 17 A. I don't know, that's a -- it's would 18 highly depend on the situation, the specific 19 compounds, specific process, so I don't think there's 20 a yes or no answer to that. 21 Q. Did you discuss this statement in your 22 report? 23 MR. VAUGHN: Object to form. 24 A. I don't cite this statement, but I do 25 discuss the issue of the need to understand the</p>	<p style="text-align: right;">Page 81</p> <p>1 work. 2 Q. And then FDA says, "Because it was not 3 anticipated that NDMA would occur at these levels in 4 the manufacturing of Valsartan API, manufacturers 5 would not have been testing for it." 6 Do you agree that manufacturers would 7 not have been testing for NDMA because it was not 8 anticipated that it would occur at these levels in 9 the manufacture of Valsartan API? 10 MR. VAUGHN: Object to form, foundation. 11 A. So the same answer. I don't agree or 12 disagree. This is beyond the scope of my work. 13 Q. Is it beyond the scope of your opinions 14 whether it was anticipated that NDMA would occur at 15 these levels in the manufacture of Valsartan API? 16 MR. VAUGHN: Object to form. 17 A. It's beyond the scope of my work from 18 the aspect of the chemistry of the reactions or the 19 description of the foreseeability based upon an 20 analysis of chemical process, which is what the 21 chemist has done in this particular case. 22 But it is my opinion that, based upon 23 the company's own admission that they didn't do a 24 full analysis, that that's a -- that's a particularly 25 important fact in this case. So in other words, if</p>

<p style="text-align: right;">Page 82</p> <p>1 you don't do something, there's no way you'll ever be 2 able to figure out whether it could or couldn't be 3 there. So it would be the issue of not doing the 4 full chemical analysis is the important first step. 5 Q. Do you consider yourself to have the 6 expertise to review the risk analysis undertaken by 7 ZHP, and independently determine whether or not it 8 was adequate? 9 MR. VAUGHN: Object to form. 10 A. I haven't done that full analysis of all 11 the chemical reactions, no. That was beyond the 12 scope of what the chemist did. However, my opinion 13 where I say that the risk assessment was inadequate 14 was based upon the company's own admissions that they 15 didn't do a full chemical analysis in their process, 16 which is what is required in order to ensure that 17 your product meets GMPs consistent with the GMP 18 process, and also can be -- you could have some level 19 of certainty that you have attempted to address all 20 the safety issues that could be raised by the 21 product. 22 Q. Did you quote the sentence in your 23 report that it was not anticipated that NDMA would 24 occur at these levels in the manufacture of Valsartan 25 API -- it's the same sentence. Did you quote this</p>	<p style="text-align: right;">Page 84</p> <p>1 Q. Let's go to page 4. Page 4 of this -- 2 A. One second, could you go to the front 3 page again for me, the first page? Yes, this is the 4 one that I think I had some of the same language as 5 the document they sent over that has other issues, 6 that it discusses as well. 7 Q. If we could turn to page 4, Dr. Gottlieb 8 states, "One challenge we've faced is that NDMA's 9 properties make it hard to detect with standard 10 laboratory testing," do you see that? It's the first 11 sentence of the second paragraph. 12 MR. VAUGHN: Object to foundation. 13 Q. "One challenge we've faced is that 14 NDMA's properties make it hard to detect in standard 15 laboratory testing"? 16 A. Well, you have to read the rest of the 17 sentence because he's describing what he means by 18 "standard lab testing," the kind of testing results 19 that were reviewed during the surveilling section. 20 Q. Do you agree with that statement? 21 A. I don't, just as I said before, I 22 wouldn't say I agree or disagree. It is FDA's 23 statement and again, this issue is beyond the scope 24 of my work. I would defer to the chemists in the 25 case who address these specific issues.</p>
<p style="text-align: right;">Page 83</p> <p>1 sentence that we've been discussing in your report? 2 A. I'm looking because I thought I called 3 it -- some of language is very similar to language 4 that shows up in a later document that I do quote 5 from. I'm looking to see. 6 I quote Dr. Gottlieb. This is 7 Dr. Gottlieb's statement. He had one, an update and 8 he used some of the same language, and I'm looking to 9 see what I quoted, so just give me a second. 10 MR. VAUGHN: Take your time, 11 Dr. Plunkett. 12 (A pause in the proceedings.) 13 A. I don't quote that specific sentence, 14 no. But I certainly cite to a document that has this 15 and many other sentences in it. 16 Q. Moving on to Exhibit 4. 17 EXH (Plunkett Exhibit 4, FDA statement dated 18 1/5/19 from Scott Gottlieb, M.D., marked for 19 identification, as of this date.) 20 MS. MILLER: Exhibit 4 is a January 5, 21 2019 FDA statement by Dr. Gottlieb. 22 Q. I'm guessing that's the other Gottlieb 23 statement you were referring to. 24 MS. MILLER: Alex, do you have that up 25 on the screens?</p>	<p style="text-align: right;">Page 85</p> <p>1 Q. And when you say it's beyond the scope 2 of your work, is that because you're not -- you don't 3 have the credentials and expertise to assess the 4 adequacy on your own of laboratory testing for 5 chemical compounds? 6 MR. VAUGHN: Object to form. 7 A. No. That's not the necessarily true. 8 There are cases that I -- there are things I have 9 done in my training and experience in the laboratory 10 where I've developed testing methods. I'm just 11 saying to you that this is is not something I have 12 done in this case, and others have. 13 So again, I am not providing testimony 14 on this particular specific issue about standard 15 laboratory testing and the difficulty with it, or 16 whether it was or wasn't standard. I would argue 17 that GCMS is a standard test that I see used every 18 day in laboratories around the world. So if the 19 issue is, is GCMS a standard lab test, it is. 20 However, there's a separate issue here 21 which is that they are then saying the kind of 22 testing that they reviewed during their surveillance 23 inspection were the kind of testing that the company 24 who sent in the ANDA, or the Drug Master File, may 25 have described.</p>

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<p style="text-align: right;">Page 86</p> <p>1 Q. Do you have a degree in organic 2 chemistry? 3 A. No, but I have training in organic 4 chemistry as part of my pharmacology and toxicology 5 background. I took four different courses in organic 6 chemistry over the years. 7 Q. How many years ago was that? 8 A. In my training, so the last course that 9 I took would have been in the 1980s. 10 Q. So that's forty years ago? 11 A. You're making me sound really old, but 12 that's true, yes. That's right. 13 Q. Have you ever conducted testing for 14 nitrosamines? 15 A. I don't know. I'd have to go back and 16 think about that. It's possible in my laboratory 17 days I did, but I don't recall that. 18 Q. When would that have been? 19 A. Before 1989. 20 Q. So in the last forty years have you 21 conducted any testing for nitrosamines? 22 A. Last thirty years I would say no, I have 23 not. I don't know about forty yet. The last thirty 24 I have not. But I can't recall. 25 Q. Have you ever developed any laboratory</p>	<p style="text-align: right;">Page 88</p> <p>1 Q. How much effort? 2 A. That's subjective. That's subjective, 3 and I think you'd have to -- you'd have to ask each 4 individual, which is why I would defer you to the 5 chemists. The chemist can speak with experience 6 based on their work in developing methods that are 7 similar, whether or not it's hard or easy. 8 I would say to you, GCMS is the standard 9 laboratory tool and if that's the method they used, I 10 wouldn't have expected it to be "hard" in terms of 11 the use of a method. But whether or not they had 12 other things they did, I would defer to the chemists. 13 Q. As a regulatory expert, are you 14 questioning FDA's use of the word "hard" here? 15 A. No, I haven't questioned their use of 16 the word "hard." This is FDA's statement. 17 Q. Are you offering an opinion that FDA's 18 statement that it was hard is erroneous? 19 A. I have not developed that opinion at 20 this point in time, no. 21 Q. Does FDA employ chemists? 22 A. Yes. Well, again, the duty for all of 23 this is not FDA's. The duty of this is the company 24 making the product. 25 Q. I understand. But my question is, does</p>
<p style="text-align: right;">Page 87</p> <p>1 testing that was intended to identify the presence of 2 nitrosamines? 3 A. I can't answer that without going back 4 to looking at the kind of work -- I did develop 5 different kinds of methods where it's possible that 6 the N-nitroso group was a way to test this part of 7 the separation procedure. But off the top of my 8 head, I can't think of a project where that was the 9 target of my work or the focus of my work, no. 10 Q. Do you know sitting here today whether 11 it is easy or hard to develop laboratory testing to 12 detect NDMA? 13 MR. VAUGHN: Object to form. 14 A. I haven't formed an opinion one way or 15 the other. And I would say that statement would 16 probably be highly dependent upon one person's 17 opinion based upon what they think is hard and what 18 they think is easy, so -- but I have not formed an 19 opinion on that issue one way or the other. 20 Q. Do you know how the FDA was using the 21 term "hard" in this sentence that we've been 22 discussing? 23 A. I can only define it based upon standard 24 English as "hard"; in other words, it required some 25 effort.</p>	<p style="text-align: right;">Page 89</p> <p>1 FDA employ organic chemists? 2 A. I answered that and said yes, and then I 3 said yes. 4 Q. My first question was chemists. My 5 second question was organic chemists. 6 MR. VAUGHN: Asked and answered. 7 A. I apologize. I assumed that chemists 8 included in -- "chemists" in my view, when I'm 9 answering that question, is encompassing chemists of 10 all different kinds. 11 Q. Based on your understanding of how the 12 FDA works, would there have been organic chemists 13 involved in the efforts to create this testing that 14 the FDA define as hard? 15 MR. VAUGHN: Objection, speculation. 16 A. I don't know. I'd have to go back and 17 see if I could find the names of the individuals and 18 what their background was. So I can't answer that 19 without looking. I don't know. 20 Q. Do you know whether the FDA employs 21 organic chemists in St. Louis in the most advanced 22 pharmaceutical laboratory of any regulatory agency in 23 the world? 24 MR. VAUGHN: Objection, form. 25 A. I can't answer that without looking. I</p>

<p style="text-align: right;">Page 90</p> <p>1 would assume they do, but I don't know.</p> <p>2 Q. Do you know whether the FDA has a</p> <p>3 division of chemistry that reviews drug master files?</p> <p>4 A. They have a division of chemistry and</p> <p>5 one of the things they can do is review drug master</p> <p>6 files. But they don't do it except in certain</p> <p>7 circumstances.</p> <p>8 Q. Do you know whether anyone from the FDA</p> <p>9 division of chemistry ever reviewed any of ZHP's drug</p> <p>10 master files?</p> <p>11 A. I don't know that I can answer that</p> <p>12 without looking at documents. I don't recall if</p> <p>13 there's a document that indicates that. So I can't</p> <p>14 answer that off the top of my head.</p> <p>15 Q. Okay.</p> <p>16 MS. MILLER: Let's go off the record.</p> <p>17 (Discussion off the record.)</p> <p>18 VIDEOGRAPHER: Going off the record.</p> <p>19 The time is 11:42 a.m.</p> <p>20 (Discussion off the record.)</p> <p>21 (Recess taken.)</p> <p>22 VIDEOGRAPHER: We are back on the</p> <p>23 record. The time is 12:01 p.m.</p> <p>24 (Continued on following page.)</p> <p>25</p>	<p style="text-align: right;">Page 92</p> <p>1 your -- my report, if you want to talk about that.</p> <p>2 Q. I'm not using a lot of documents today,</p> <p>3 so that will be okay. Dr. Plunkett, can you please</p> <p>4 turn to page 28 of your report. Do you see these</p> <p>5 images here?</p> <p>6 A. Yes, I do.</p> <p>7 Q. Where did you get these images from?</p> <p>8 A. These came from Casarett images --</p> <p>9 actually, here, I have footnotes. Images -- I have</p> <p>10 footnote 35, tells you there. So they are from the</p> <p>11 web. The Internet, you can search the Internet for</p> <p>12 chemical structures, rather than drawing them</p> <p>13 yourself, so that's what I did.</p> <p>14 Q. And what is this website?</p> <p>15 A. Well, I -- you need to go to it, it's a</p> <p>16 website that had -- when I Googled structures,</p> <p>17 chemical structure, NDMA, NDEA, nitrosamines, this is</p> <p>18 the website that came up and I checked those,</p> <p>19 obviously. I'm aware of the general structure of the</p> <p>20 nitrosamine, the first core structure. You can</p> <p>21 actually find that in Casarett & Doull as well, which</p> <p>22 is -- which is a textbook that I cite for, and then</p> <p>23 these others came from the same site, but I -- I'm</p> <p>24 aware of what N-dimethyl -- N-dimethyl looks like,</p> <p>25 and -- and N-diethyl looks like, so, yeah, I'm enough</p>
<p style="text-align: right;">Page 91</p> <p>1 EXAMINATION (Cont'd.)</p> <p>2 BY MS. MILLER:</p> <p>3 Q. Earlier today we marked your expert</p> <p>4 report, Dr. Plunkett, as Exhibit 1. I'm guessing you</p> <p>5 have a copy of it in front of you, is that correct?</p> <p>6 A. I do.</p> <p>7 Q. Do you have anything else in front of</p> <p>8 you today?</p> <p>9 A. I have only the notice of deposition</p> <p>10 document, and I printed out the 2019 letter just</p> <p>11 because I had looked at that yesterday, and I have</p> <p>12 two other documents I printed out just because they</p> <p>13 are in my report. One was the '99 "Guidance For</p> <p>14 Industry on Purity," because I cite that in my</p> <p>15 report, and I also printed out something I cited in</p> <p>16 my report from the NDMA website, "Q&A on CGMP</p> <p>17 Practice."</p> <p>18 Q. Sounds good. And I assume you don't</p> <p>19 have any other programs open on your computer?</p> <p>20 A. No. -- well, I was going to ask this</p> <p>21 question. So now that you're sharing the screen, if</p> <p>22 I want to go look at a document, I don't know how to</p> <p>23 do that because you take up all my screen. So if it</p> <p>24 gets to that, I'm going to have to ask if I want to</p> <p>25 look at it separately. But this one I have. I have</p>	<p style="text-align: right;">Page 93</p> <p>1 of a chemist that I could tell you these are correct.</p> <p>2 Q. What is shionogi-ph.co?</p> <p>3 A. That's the website. It's probably a</p> <p>4 chemical manufacturer website. And you want me to go</p> <p>5 look, I'd have to go look and I can't do that with</p> <p>6 you having the screen taking up my entire -- but you</p> <p>7 should be able to do that.</p> <p>8 Q. I'm just asking if you know what it is.</p> <p>9 A. It's a website that I believe has</p> <p>10 chemical structure information, and it may be a</p> <p>11 chemical manufacturer, someone who sells these</p> <p>12 compounds, but I'm not sure. I'd have to go back and</p> <p>13 look.</p> <p>14 Q. Okay. And then what is footnote 36</p> <p>15 representing? In other words, did these images come</p> <p>16 from footnote 35 or footnote 36?</p> <p>17 A. Oh, okay. The core structure comes from</p> <p>18 36 and NDMA and NDEA come from 35.</p> <p>19 Q. Okay, that was not clear. And do you</p> <p>20 know what "eurofins" --</p> <p>21 A. Yes, Eurofins is a testing laboratory</p> <p>22 that has international -- offices around the world,</p> <p>23 they also do regulatory consulting. I use them with</p> <p>24 my clients in different regulatory space to handle</p> <p>25 work and develop analytical methods at times.</p>

<p style="text-align: right;">Page 94</p> <p>1 Q. And why do both of these websites end in 2 .jp? 3 MR. VAUGHN: Object to form. Calls for 4 speculation. 5 A. I don't know. I can't answer. 6 Q. Okay. 7 EXH (Plunkett Exhibit 5, Boerner article 8 from Chemical and Engineering News dated 4/20/20, 9 marked for identification, as of this date.) 10 MS. MILLER: I'd like to introduce as 11 Exhibit 5 an article by -- I'm really just butchering 12 her name -- Leigh Kreitsch Boerner. We're going to 13 show you the spelling. Alex is putting it up on the 14 screen right now. 15 This is an article from Chemical and 16 Engineering News. Have you ever heard of Chemical 17 and Engineering News before -- 18 MR. VAUGHN: Give me just one second, 19 Jessica, unless you're finally -- 20 Q. Before we introduce the document, while 21 he's looking for it, I'm just asking if you have 22 heard -- 23 MR. VAUGHN: Understood -- 24 MS. MILLER: I won't ask anything about 25 the document, obviously.</p>	<p style="text-align: right;">Page 96</p> <p>1 MS. MILLER: Let's figure that out once 2 we go off the record. 3 VIDEOGRAPHER: Okay, going off the 4 record. The time is 12:07 p.m. 5 (Discussion off the record.) 6 VIDEOGRAPHER: We're back on the record. 7 The time is 12:18 p.m. 8 EXAMINATION (Cont'd.) 9 BY MS. MILLER: 10 Q. Dr. Plunkett, are you familiar with an 11 organization called Health Canada? 12 A. Yes. 13 Q. What is Health Canada? 14 A. Health Canada is essentially the paid 15 equivalent of the FDA but it's not exactly the same. 16 Health Canada actually does assessments, health 17 assessments for products outside of some of the FDA 18 regulated products as well. 19 Q. Have you ever relied on Health Canada in 20 forming your opinions in any litigation? 21 A. Typically, I'm not allowed to in the 22 U.S. They will mention the U.S. regulatory agencies, 23 but I have generally in my work relied on Health 24 Canada and certainly, I have done work for clients 25 related to submissions of Health Canada.</p>
<p style="text-align: right;">Page 95</p> <p>1 MR. VAUGHN: Fine. 2 A. If the question is have I ever heard of 3 it, yes. They are a trade press type publication. 4 Q. And do you regularly read this 5 publication? 6 MR. VAUGHN: Object to form. 7 A. I don't reg -- I don't seek it out on a 8 monthly basis, but I have read it before when I have 9 had an issue. Sometimes it's referred to in other 10 places that I'm reviewing. So for example, I might 11 be looking at an article that's put out by RAPS on 12 their website, the Regulatory Affairs Professional 13 Society, and then might refer back, so just depends. 14 Q. And have you seen this article before? 15 A. No, I have not seen this article. So if 16 you're going to ask me specific questions, I would 17 need to read through it. 18 Q. Okay. I am going to ask you specific 19 questions. My understanding is that under the CMO in 20 this case, if you're going to read an article, we're 21 allowed to go off the record. So let's go off the 22 record for you to read it. 23 A. So before you go -- I need to know how 24 to get to it, because I don't seem to be able to get 25 to my screen.</p>	<p style="text-align: right;">Page 97</p> <p>1 Q. Have you relied on Health Canada in 2 forming any of your opinions in the talc litigation? 3 A. Yes, because there was a separate report 4 for Canada healthcare, so I'm working on the talc 5 litigation that is related to claims in Canada and 6 Health Canada. 7 Q. And did you give credence in that 8 litigation to the Health Canada report? 9 A. I don't know how you define "credence," 10 but the if you mean did I refer to it? Yes. And I 11 certainly did rely upon some of the documents and the 12 reviews that Health Canada did, yes. 13 And I'm sorry, Ms. Miller, you were 14 asking me about the talc litigation, correct? 15 Q. Correct. 16 A. Yes. So the answer to the last question 17 about reliance had to do with the talc litigation. 18 Q. Okay. 19 A. That's fine. 20 Q. And do you consider Health Canada to be 21 a reputable organization? 22 MR. VAUGHN: Object to form. 23 A. Well, it certainly -- I would say it's 24 one of the regulatory bodies that I have seen applies 25 good standard scientific practice, yes. But they</p>

25 (Pages 94 - 97)

<p style="text-align: right;">Page 98</p> <p>1 have different regulations so the context of the work 2 they do is a bit different from the FDA. And so 3 that's important to recognize when you look at what 4 Health Canada does and why they make certain 5 decisions. They have different laws, in other words. 6 Q. If you turn to page 3 of this article -- 7 I'm sorry, of this -- yeah, so if we could turn to 8 page 3 of this article, who publishes Chemical and 9 Engineering News? 10 A. I don't know who. I just know it as a 11 trade press journal that I have seen before. 12 Q. Have you heard of the American Chemical 13 Society? 14 A. Yes, I have. 15 Q. What is that? 16 A. It's a scientific organization that's 17 related to the chemical industry and chemists. 18 Q. Does the American Chemical Society 19 publish this journal? 20 A. I said I didn't know. I'd have to look. 21 I don't know. 22 Q. Do you know whether the reporters and 23 editors in this journal have advanced degrees in 24 chemistry? 25 MR. VAUGHN: Objection, foundation.</p>	<p style="text-align: right;">Page 100</p> <p>1 assessment turns on whether the exposure can be 2 controlled? 3 MR. VAUGHN: Objection to form. 4 A. I don't understand your form. 5 Q. You testified you are aware that a risk 6 assessment can turn on whether this exposure can be 7 controlled; for example, you said sometimes you can't 8 exclude NDMA from a product. And I'm wondering if 9 there's anything in the literature that says that a 10 risk assessment should -- should assess whether or 11 not the exposure can be controlled. 12 MR. VAUGHN: Objection, form, misstates 13 prior testimony. 14 A. I don't think I used the word "turn," 15 but I may have used a similar word. But here's my 16 answer for this: 17 In my experience and training and all of 18 my work for regulatory agencies, in a variety of 19 contexts, not just at FDA, risk assessments that are 20 done for products often are affected by decisions 21 that are made about whether there is exposure or not. 22 So if exposure can be controlled, such as that it 23 does not occur, then a product may be able to remain 24 on the market. 25 So for example, if a product -- if the</p>
<p style="text-align: right;">Page 99</p> <p>1 A. Same answer. I'd have to look. I don't 2 know. 3 Q. If you could turn to page 3, this 4 article says, "NDMA is all around us. We're exposed 5 to it in many ways but the main sources tend to be 6 tobacco, cured meats such as bacon, fermented foods 7 such as beer and cheese, shampoo and cleansers and 8 detergents and pesticides." Do you know what that -- 9 A. I think you said "posed," and I think 10 it's "exposed." So we're exposed. 11 Q. Oh. 12 A. I do know that there is exposure through 13 sources in our diet and our environment, yes. I 14 don't know if that's entirely accurate based upon any 15 particular product. Certainly I think generally, it 16 is found in other products. 17 Q. Do you know whether any of these 18 products can be manufactured in a way that doesn't 19 result in NDMA formation? 20 A. I've not done an assessment of that, so 21 I can't answer that for you. I'd have to go, I'd 22 have to look at individual products. It would be a 23 product, not a category-by-category necessarily, but 24 a product-by-product assessment. 25 Q. Is there any literature that says a risk</p>	<p style="text-align: right;">Page 101</p> <p>1 issue is a -- something within a product or some 2 aspect of a product that potentially could pose a 3 cancer risk by inhalation, but you're not inhaling 4 this particular product or compound in this product, 5 it's not going to happen, then you can control for 6 the exposure even though it may have something in it 7 that could pose a risk by inhalation. 8 So all risk assessments that I'm aware 9 of, that I'm involved in, were for products that are 10 regulated in the U.S., have an exposure component to 11 them considering the likelihood for exposure, ways 12 that you can be exposed, and that goes into the risk 13 assessment. 14 It's kind of like the second step. 15 First you do the hazard, then you do the exposure, 16 Andy you do the dose response if you can, and then 17 you do the -- you characterize the risk based on the 18 exposure and hazard. 19 Q. Did you do all four of those steps here? 20 A. I did not do a dose/response assessment, 21 which is what would be the specific cause issue to 22 do. And I did not do individual causation exposure 23 assessments for anybody in the case. But certainly I 24 looked at what the regulatory bodies did and the 25 companies did or didn't do in this area.</p>

<p style="text-align: right;">Page 102</p> <p>1 Exposure, for example, is going to</p> <p>2 happen in terms of taking something orally. So we</p> <p>3 know that these are pills that are meant to be taken.</p> <p>4 So this is not like the issue of can they inhale.</p> <p>5 They are ingesting it, you know that's the case.</p> <p>6 We know that nitrosamines from the</p> <p>7 general literature are indeed able to be absorbed</p> <p>8 once ingested. So those things I know just generally</p> <p>9 occur. So I didn't, you know, consider that as part</p> <p>10 of my training and experience.</p> <p>11 But I did not do individual assessments</p> <p>12 for how people, individuals might take the drug,</p> <p>13 daily, weekly, those kinds of things.</p> <p>14 Q. Did you do all of the steps in a risk</p> <p>15 assessment methodology in this matter?</p> <p>16 MR. VAUGHN: Object to form.</p> <p>17 A. I was not asked to do the full risk</p> <p>18 assessment for individuals, so I did not go to all</p> <p>19 the details of that. That was correct. I used</p> <p>20 the -- I used the methodology that I typically use</p> <p>21 when I'm developing regulatory opinions. And then in</p> <p>22 toxicology, I did a -- a hazard assessment and</p> <p>23 whether or not there was evidence to indicate whether</p> <p>24 or not this was a compound that would pose a risk</p> <p>25 only at a particular level. That's what we talked</p>	<p style="text-align: right;">Page 104</p> <p>1 expert reports that -- in this case, actually were</p> <p>2 available before my deposition. Sometimes those</p> <p>3 aren't. So I did look at the defense expert reports</p> <p>4 that dealt with my area, and just like I looked at</p> <p>5 some of the Plaintiffs' expert reports.</p> <p>6 Q. What methodology did you apply to</p> <p>7 determine that there's an increased risk of cancer?</p> <p>8 A. That would be my training and experience</p> <p>9 and the issues related to weighing the evidence and</p> <p>10 the issues based upon statements and information</p> <p>11 that's available. Is this something that's taught in</p> <p>12 textbooks, that you give a weight to that kind of</p> <p>13 evidence? Is it something that you only have one or</p> <p>14 two papers and then you have to determine whether or</p> <p>15 not those papers are reliable enough to make the</p> <p>16 determination? When authoritative bodies have</p> <p>17 reviewed this for the last fifty years, that's</p> <p>18 important weight in the evidence.</p> <p>19 So in those opinions, yes, I did, I</p> <p>20 weighed the evidence and the sources and the -- in my</p> <p>21 experience, the reliability of those particular types</p> <p>22 of sources.</p> <p>23 Q. Do you identify in your report all the</p> <p>24 evidence that you weighed in determining that there's</p> <p>25 an increased risk of cancer?</p>
<p style="text-align: right;">Page 103</p> <p>1 about already. I told you that because of it being a</p> <p>2 genotoxin and acting as a carcinogen. There is no</p> <p>3 threshold of no risk.</p> <p>4 Q. Did you apply a weight-of-the-evidence</p> <p>5 methodology?</p> <p>6 MR. VAUGHN: Objection to form.</p> <p>7 A. Based on the doc --</p> <p>8 THE WITNESS: I'm sorry, Brett --</p> <p>9 MR. VAUGHN: You're fine.</p> <p>10 A. Based on the documents I reviewed, yes,</p> <p>11 I did. I looked across the evidence in the case for</p> <p>12 certain opinions. Not every opinion would make sense</p> <p>13 to use weight-of-the-evidence.</p> <p>14 Weight-of-the-evidence is typically</p> <p>15 used, for example, when I have my section where I</p> <p>16 talk about the toxicology and the potency of NDMA and</p> <p>17 NDEA, or nitrosamines, that's a weight-of-the-</p> <p>18 evidence form.</p> <p>19 When I talk about the weight of the</p> <p>20 evidence in terms of what did I see that the company</p> <p>21 knew or didn't know, I -- there I am looking at</p> <p>22 information that is coming from all the available</p> <p>23 sources, so I'm weighing that together to tell a</p> <p>24 story or to see what story is told.</p> <p>25 I also looked at, for example, defense</p>	<p style="text-align: right;">Page 105</p> <p>1 A. In my reliance materials, it shows you</p> <p>2 all of the information that I have reviewed and</p> <p>3 weighed, yes. So you have to -- you can't just look</p> <p>4 at the report, you have to look at my appendix C as</p> <p>5 well, depending on the question you're asking.</p> <p>6 Q. Does the report itself set forth how you</p> <p>7 conducted a weight-of-the-evidence analysis, what</p> <p>8 evidence you reviewed, and what conclusion you</p> <p>9 reached based on that evidence with respect to</p> <p>10 increased risk?</p> <p>11 MR. VAUGHN: Object to form.</p> <p>12 A. I believe that the totality of my</p> <p>13 report, which includes all my appendices, do, yes.</p> <p>14 Q. In the actual language of the report,</p> <p>15 excluding your appendices, can you point to me to</p> <p>16 where you set forth which evidence you reviewed in</p> <p>17 determining, and which evidence you weighed in</p> <p>18 determining that there's an increased risk of cancer?</p> <p>19 MR. VAUGHN: Object to form.</p> <p>20 A. I think I tell you that. So -- hold on,</p> <p>21 let me look.</p> <p>22 (A pause in the proceedings.)</p> <p>23 A. Trying to find the right section. Hold</p> <p>24 on.</p> <p>25 (A pause in the proceedings.)</p>

<p style="text-align: right;">Page 106</p> <p>1 A. In section 6 in my report, if that's the 2 one you're asking, that question, I think that's 3 where this question would come, the answer to your 4 question would come from. 5 So I set forth the textbooks, the 6 authoritative bodies that I have reviewed and relied 7 upon, and I think some -- I usually in here will make 8 a comment about my training an experience, but I 9 think I did that up front. Up front I tell you that 10 when I -- the opinions here were developed based on 11 not just the documents, but my training and 12 experience as well. 13 Q. My question -- that's not my question. 14 My question is, where can I see evidence that you 15 weighed and how you weighed it in your report? 16 A. I'm telling you, the evidence that I 17 have weighed and reviewed and relied upon are found 18 cited in this section on toxicology of nitrosamines 19 and then there may be additional materials that are 20 listed in appendix C as well. In my depositions, 21 typically -- typically that's the opportunity for you 22 to ask me this question and I will tell you what it 23 is that I have -- that I have reviewed and relied 24 upon, in addition to how I describe it in my report. 25 And I'm telling you, it's my training,</p>	<p style="text-align: right;">Page 108</p> <p>1 Q. Is there a place in your report where I 2 can see how you weighed the evidence -- 3 MR. VAUGHN: Objection. 4 Q. -- which evidence you gave more weight 5 to, which evidence you gave less weight to, the 6 actual methodology; not your expertise, but see the 7 methodology. Can you point to paragraphs in your 8 report that do that? 9 A. So I -- what you're asking me doesn't 10 make sense for a compound like this, where I do tell 11 you the documents I relied upon and I cite to those 12 specifically. And those are themselves 13 weight-of-the-evidence reviews and dissertations. 14 I tell you in my methodology, it's 15 there, that the way I do weight-of-the-evidence is 16 consistent with the way bodies around the world may 17 do it. I mean, I don't understand what you're asking 18 me. 19 I didn't -- there was no need for me to 20 perform another IARC review of all of the studies 21 when IARC is a body that is relied upon by FDA, 22 Health Canada, and toxicologists generally and I have 23 reviewed that and made my -- my assessment that their 24 review covers the breadth and the scope and uses the 25 methodology that's consistent with how a toxicologist</p>
<p style="text-align: right;">Page 107</p> <p>1 my experience, my prior knowledge of these compounds, 2 what the authoritative bodies and the textbooks have 3 said about it, what FDA has said about it, what the 4 companies themselves in their own internal e-mails 5 have said about the product. 6 The NTP document and the IARC document 7 that I cite to are weight-of-the-evidence documents 8 and so I have relied upon those, and I have reviewed, 9 for example, I've reviewed the entire section of the 10 IARC document that talks about all the different 11 animal studies and human evidence and whatnot that 12 dealt with nitrosamines, and specifically the NDMA 13 and NDEA. So that accomplishes this section that I'm 14 talking about. 15 Q. Dr. Plunkett, you're not really 16 answering my question, which was very simple: Is 17 there a place in your report where I can see how you 18 weighed each piece of evidence? How you -- 19 MR. VAUGHN: Object. 20 Q. -- your methodology -- 21 MR. VAUGHN: Object to form, asked and 22 answered. I objected to form, asked and answered. 23 Move on. 24 MS. MILLER: Come on, Brett, let her 25 answer it.</p>	<p style="text-align: right;">Page 109</p> <p>1 would look across the literature. 2 So I don't quite -- I mean, your 3 question would make sense if you were asking me about 4 a compound that no one else had made ever, but this 5 is not the case here. 6 Q. So is it fair to say you're relying on 7 other people's weight of the evidence and -- 8 A. No. I performed my own 9 weight-of-the-evidence assessment based upon the 10 sources I have cited for you, and I'm just trying to 11 explain to you the reason why I don't lay out each 12 individual study is because that was done very 13 thoroughly and very well in the documents that I cite 14 to you. 15 So do I rely on the fact that they are 16 complete assessments? I do rely on those documents 17 but it's also something that I have done in the past. 18 I'm very familiar with the IARC assessment of 19 nitrosamines and MDNA. I have used it, reviewed it a 20 number of times over the years, and it is a reliable 21 document and a good assessment that goes through 22 strengths, limitations, weaknesses, all of those 23 things. 24 I have reviewed that. I agree with 25 their assessment in terms of what I also know is</p>

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<p style="text-align: right;">Page 110</p> <p>1 consistent with every other regulatory body that I've 2 ever seen that has assessed the carcinogenicity -- 3 carcinogenic potential of NDMA and NDEA. FDA talks 4 about that specifically as well. And I have relied 5 on that when looking at FDA's conclusions about what 6 they say about these compounds. 7 Q. Did you review animal studies related to 8 NDMA? 9 A. As they were cited in the NTP document, 10 yes, because very specific and detailed data table 11 there, so I did. 12 Q. Did you go back to the original studies 13 or did you just rely on what NTP said about them? 14 A. I answered that for you. I said IARC 15 first off, but also NTP, they both do it. I have 16 seen the reviews of -- by both of those -- those 17 bodies, and I've seen the references, I've looked at 18 the summary of the information, but I did not redo 19 their analysis. There is no need to. Again, there's 20 no controversy in my view. I challenge you to tell 21 me there's a controversy that NDMA does not increase 22 the risk of cancer, because it does. 23 Q. Do you know whether the dose of NDMA 24 addressed in the animal studies is similar to the 25 dose that has been found in Valsartan?</p>	<p style="text-align: right;">Page 112</p> <p>1 Q. So you're saying that the animal studies 2 had doses of NDMA that were higher than the doses 3 that Valsartan users are exposed to? 4 A. I can't tell you that that's the case 5 for every Valsartan user because I don't know what 6 every Valsartan user took. But I can tell you that 7 the doses that were used in the animal studies were 8 chosen based on sound scientific principles and 9 clearly show every study, regardless of the dosage 10 use and the route of exposure, even a single dose in 11 a prenatal study showed that NDMA was carcinogenic 12 and by definition, it's something that's carcinogenic 13 and if you're exposed to it as a human, you're 14 increasing your risk of cancer. 15 Q. If something is carcinogenic and you're 16 exposed to it as a human, you're increasing your risk 17 of cancer regardless of dosage? 18 A. You're -- increasing the risk is not the 19 same as identifying a dose. Increasing the risk of 20 cancer is a statement about hazard. It is telling 21 you that when you're exposed to this, the properties 22 of this chemical have the ability to be carcinogenic. 23 And so you increase your risk. There is no safe dose 24 of NDMA that's been defined. There's -- there is 25 instead a -- you can make a determination whether</p>
<p style="text-align: right;">Page 111</p> <p>1 MR. VAUGHN: Object to form. 2 A. So that's a different question. So as 3 all animal studies are done, they have to do an 4 exaggeration of dose because animals don't have the 5 same susceptibilities or sensitivities that humans 6 do. It's a general principle of toxicology, when you 7 design a cancer bioassay in animals, that you will 8 use dose ranges that start out, you always have a 9 zero and then you have a level that may or may not be 10 similar to what humans may be exposed, but you 11 exaggerate it because the idea is, you want to be 12 able to show that you have tested the system of the 13 animal to such an extent that you can rule out, if 14 possible, that the product is or is not a carcinogen. 15 So you can make that determination. 16 So you need to see your -- you're hoping 17 to see some type of pathology that would indicate yes 18 or no, there's a carcinogenic result. 19 You also start in cancer risk assessment 20 bioassay development and dose collection with results 21 from the genotoxicity evaluations that are done, and 22 you use those to also help set your doses, but they 23 are not the same. The human exposure doses could be 24 very different, depending upon the situation you talk 25 about.</p>	<p style="text-align: right;">Page 113</p> <p>1 it's acceptable to increase cancer risk more than one 2 in a million or not. That's the decision. And those 3 decisions for regulators are in a different context. 4 But as a scientist, that's what you do, you calculate 5 the slope of the dose/response curve and you 6 extrapolate to zero because there is no "threshold" 7 for cancer. 8 Q. So is it your opinion that any exposure 9 to NDMA increases the risk of cancer? 10 A. I have not -- I haven't formed an 11 opinion of any specific dose but exposure to NDMA 12 generally, that's exactly right, increases your risk 13 of cancer. 14 Now, you say "any exposure," you need to 15 explain to me what you mean by that because, could I 16 come up with an exposure that may be -- it's 17 possible. But in terms of these products in this 18 case where you're orally ingesting these products, 19 that is my opinion, purely and simply, that the 20 exposure to Valsartan products containing these 21 impurities increased -- increases the risk of cancer 22 in people who take the drug. And then, there you 23 have to go and talk about individuals and that's not 24 what I have done. There's an indication to do that. 25 Q. Would any exposure to NDMA through</p>

29 (Pages 110 - 113)

<p style="text-align: right;">Page 114</p> <p>1 Valsartan increase the risk of cancer?</p> <p>2 MR. VAUGHN: Objection, vague as to</p> <p>3 "exposure."</p> <p>4 A. I answered that. I said I believe that</p> <p>5 in this case, based upon what I know is occurring,</p> <p>6 that your risk is increased with your exposure to the</p> <p>7 impurities in Valsartan. It increases your risk</p> <p>8 because of the issue that there is no threshold or</p> <p>9 safe dose that's been identified for a cancer-causing</p> <p>10 ingredient.</p> <p>11 But there's another concept, which is</p> <p>12 what the regulator applies, and that is making a, in</p> <p>13 this case, making a risk/benefit decision based on --</p> <p>14 actually it's a risk/risk decision, not a</p> <p>15 risk/benefit -- they are looking at whether or not</p> <p>16 the exposure -- the FDA is -- whether or not the</p> <p>17 exposure to impurities in Valsartan is riskier than</p> <p>18 someone who doesn't take the drug, and those are</p> <p>19 things that regulators do.</p> <p>20 That is not what I'm doing. I'm telling</p> <p>21 you as a scientist that this particular drug with</p> <p>22 these impurities present, if those impurities are</p> <p>23 present, you're increasing the risk of cancer in</p> <p>24 individuals who take the drug.</p> <p>25 Q. If we could go to the third paragraph on</p>	<p style="text-align: right;">Page 116</p> <p>1 MR. VAUGHN: Objection, form, vague as</p> <p>2 to "these pharmaceuticals."</p> <p>3 A. I don't believe I've formed opinion on a</p> <p>4 specific level at this point in time in Valsartan, if</p> <p>5 that's what you're asking me. So if you're talking</p> <p>6 about Valsartan, at the levels that may have been</p> <p>7 detected in any one pill, at any one particular point</p> <p>8 in time, that was beyond the scope of what I did,</p> <p>9 but -- but, I would point you to the fact that the</p> <p>10 regulatory agencies are not saying there was no risk.</p> <p>11 They are making a judgement based upon a</p> <p>12 situation they are in which is balancing drug</p> <p>13 shortages, they are balancing people stopping to take</p> <p>14 the drug, there's a lot of things they are balancing,</p> <p>15 and why they all concluded that this stuff shouldn't</p> <p>16 be there and it needs to come out.</p> <p>17 Q. Let's look at the next sentence from</p> <p>18 there. "A person taking a drug that contains NDMA at</p> <p>19 or below the acceptable intake every day for 70 years</p> <p>20 is not expected to have increased risk of cancer."</p> <p>21 Do you see that?</p> <p>22 A. I see that.</p> <p>23 Q. Do you agree with that statement?</p> <p>24 A. I don't agree with that statement as</p> <p>25 specified because there's more to it, if you actually</p>
<p style="text-align: right;">Page 115</p> <p>1 this document, on the screen, Exhibit 5, first</p> <p>2 sentence says, "According to Health Canada, the</p> <p>3 average" --</p> <p>4 A. Hold on a second, I need to find it --</p> <p>5 okay, I see it NOW. Okay.</p> <p>6 MR. VAUGHN: Are you on page 3?</p> <p>7 MS. MILLER: Yep.</p> <p>8 Q. "According to Health Canada, the average</p> <p>9 levels of NDMA found in these pharmaceuticals are not</p> <p>10 expected to pose a significant increase in cancer</p> <p>11 risk."</p> <p>12 Do you disagree with that statement?</p> <p>13 A. I don't -- I haven't done that</p> <p>14 assessment so I can't agree or disagree with that,</p> <p>15 because I haven't looked at a specific population of</p> <p>16 numbers of levels to make that assessment. That's a</p> <p>17 different assessment.</p> <p>18 But I point you to the fact, you'll</p> <p>19 notice they don't say there's no risk, and that's the</p> <p>20 point I'm making to you, that no one is saying</p> <p>21 there's no risk.</p> <p>22 Q. Do you have an opinion as to whether the</p> <p>23 average levels of NDMA found in these pharmaceuticals</p> <p>24 is expected to pose a significant increase in cancer</p> <p>25 risk?</p>	<p style="text-align: right;">Page 117</p> <p>1 look at what FDA and Health Canada say. They</p> <p>2 actually put it in the context of the number of</p> <p>3 cancers that you would expect to see over a lifetime</p> <p>4 and it wasn't zero.</p> <p>5 So again, I would -- I would disagree</p> <p>6 that you would not expect -- you have an increased</p> <p>7 risk. The question is, how -- what is that increase,</p> <p>8 and how do you weigh that as a regulatory agency in</p> <p>9 terms of making decisions on drug availability.</p> <p>10 Regardless of that, however, again, both</p> <p>11 of these regulatory agencies are on the record saying</p> <p>12 that the NDMA should not be there, and they want it</p> <p>13 gone.</p> <p>14 Q. According to this article, a</p> <p>15 representative from Health Canada stated that a</p> <p>16 person taking a drug that contains NDMA at or below</p> <p>17 the acceptable intake every day for 70 years is not</p> <p>18 expected to have an increased risk of cancer.</p> <p>19 Do you agree with the Health Canada</p> <p>20 statement there or not?</p> <p>21 MR. VAUGHN: Objection, foundation.</p> <p>22 A. I don't know what else was in the e-mail</p> <p>23 so I haven't formed an opinion. I wouldn't form an</p> <p>24 opinion I agree or disagree with this statement taken</p> <p>25 by itself. But I would tell you I have seen other</p>

<p style="text-align: right;">Page 118</p> <p>1 descriptions from the regulatory agencies where they 2 are -- they are not saying that there is no increase 3 in risk, which would be the -- which would be what 4 you would be taking from this if that was -- if that 5 was the case. 6 Q. Have you seen a statement from Health 7 Canada saying that it believes there is an increased 8 risk? 9 A. I'd have to go back and look at the 10 Health Canada website again. But what I have read 11 from Health Canada is consistent with them also 12 understanding that there's an increased risk of 13 cancer with exposure to NDMA, and that it is 14 something that they do not want in the drug supply. 15 Q. Is it your testimony sitting here today 16 that Health Canada has stated that taking Valsartan 17 that had NDMA or NDEA impurities would increase a 18 patient's risk of cancer? 19 A. If you're going to ask me that specific 20 question, I'll have to go back to the Health Canada 21 website to look. I'm just telling you my 22 interpretation or my take-away from looking at the 23 positions of both bodies is that this is something 24 that isn't supposed to be there. The companies can 25 make -- ZHP can make the product without this</p>	<p style="text-align: right;">Page 120</p> <p>1 that in both cases, the agency is aware that there is 2 a way to make the drug without the contaminant, or 3 without the impurity, and that's what's important. 4 If you can make it without it, then there is no risk 5 because it's not there. 6 Q. Do you believe that a person who took 7 Valsartan for 70 years that contained NDMA would have 8 had an increased risk of cancer? 9 MR. VAUGHN: Objection to form. 10 A. I answered that for you already. I told 11 you I have not done a calculation in that way, so I 12 can't answer that. That's somewhat, other people are 13 doing that, and I would refer you to the other 14 experts who are doing these kinds of risk assessment 15 coverage. 16 Q. So you do not have an opinion as to 17 whether somebody who took Valsartan for 70 years that 18 contained NDMA would be expected to have an increased 19 risk of cancer? 20 A. I have not formed that exact opinion, 21 but I have formed the opinion that the presence of 22 NDMA and NDEA and other nitrosamines like those that 23 are potent genotoxins in Valsartan drug products 24 increases the consumer or the patient's risk of 25 cancer. That's my opinion, and I think that's</p>
<p style="text-align: right;">Page 119</p> <p>1 contaminant, or this impurity, I'm sorry, different 2 regulatory term, contaminant. They can make it 3 without it, and if they can make it without it, 4 that's what the agencies want to happen. 5 Q. I understand that, but has Health Canada 6 stated that somebody who took Valsartan with NDMA 7 impurities as was at an increased risk of cancer? 8 MR. VAUGHN: Objection, asked and 9 answered. 10 A. That same answer. To find a specific 11 statement I'd have to go look, but that would not be 12 consistent with the overall methods or the overall 13 conclusions I have seen the agencies make. 14 Q. Sitting here today, do you recall any 15 statements by Health Canada that taking Valsartan 16 with NDMA or NDEA impurities would increase a 17 person's risk of cancer? 18 MR. VAUGHN: Objection, asked and 19 answered. 20 A. Same question -- same answer. I 21 would go back and look at the website and scour it 22 again. But when I looked at the website, I wasn't 23 looking for a particular sentence. So I can't answer 24 that at this point in time without looking. 25 But again, I would point to the fact</p>	<p style="text-align: right;">Page 121</p> <p>1 consistent were what I've said in my report. 2 Q. So you have an opinion that it increases 3 the risk of cancer generally, but you don't have an 4 opinion whether it increases the risk of cancer if 5 you take it for 70 years? 6 A. Because I have not done that 7 calculation. When you're asking me that question, 8 that was beyond the scope of what I did. So again, I 9 don't know what else to tell you, but I know there 10 are other experts in the litigation who are doing 11 these calculations, and I'm sure they'd be happy to 12 answer the question, because they've all done those 13 calculations. 14 Q. Are you offering an opinion in this 15 litigation as to whether Health Canada was correct or 16 incorrect in making this statement that we just read? 17 MR. VAUGHN: Object to form, foundation. 18 A. I have not formed an opinion like you're 19 describing at this point in time. And typically I 20 would not because all of this that you're talking 21 about, the issue is the duty -- what is the duty of 22 the company; and it's the company's responsibility to 23 make sure that their products are safe for use, 24 regardless of what Health Canada says or FDA says. 25 Q. We're not talking about obligations and</p>

<p style="text-align: right;">Page 122</p> <p>1 duties right now. I'm asking you whether or not you 2 agree with Health Canada that a person taking a drug 3 that contains NDMA at or below the acceptable intake 4 every day for 70 years is not expected to have an 5 increased risk of cancer. 6 MR. VAUGHN: Object to form, foundation. 7 There's no evidence that Health Canada made the 8 statement. 9 A. I've answered this question I think for 10 you five times already, and I'm not changing my 11 answer. You know, again, I have not done a 12 quantitative risk assessment. I have not -- which is 13 what you would be doing here. I have done an 14 assessment based on the hazard that is posed, which 15 is an appropriate standard in terms of the regulatory 16 world when you're looking at the statements these 17 agencies make about -- about this situation, that 18 it's unacceptable for this to be there. 19 And then they acknowledge that you can 20 make the compound without it. Diovan with the TIN 21 process apparently was made without it. So again, 22 I -- I'm not trying to evade your question, I'm just 23 telling you that's all important context here. When 24 you ask these questions, do I agree or disagree with 25 the regulatory agency, it's not as simple as that,</p>	<p style="text-align: right;">Page 124</p> <p>1 to whether any Diovan ever had trace amounts of NDMA 2 or NDEA? 3 A. I looked for information in the files or 4 the documents that I had access to, and I also 5 looked, I saw a document, the one I cite to, I think 6 I tell you, let me look for it... 7 (A pause in the proceedings.) 8 A. The analyses, I've seen an analysis by 9 Health Canada of Diovan samples and I cite you to the 10 source for that. The Diovan was listed there as it 11 not being defective. And again, if you look at all 12 of the things that are said, other evidence in this 13 case where these different changes in the process are 14 discussed, the company themselves recognizes that 15 there's a difference between the TIN process that is 16 used for Diovan versus their process in terms of the 17 potential for the formation of nitrosamines. 18 Q. Is it your opinion that because Health 19 Canada did not find nitrosamines in the Diovan it 20 tested, that means that no Diovan ever had 21 nitrosamine impurities? 22 A. No, my opinion is that the testing of 23 Diovan demonstrates that this particular drug had 24 been manufactured without nitrosamine impurities. 25 That's my paragraph 61.</p>
<p style="text-align: right;">Page 123</p> <p>1 and I have not formed an opinion that I agree or 2 disagree with any particular one sentence from 3 regulatory agency. 4 Q. Are you offering an opinion as to 5 whether Diovan contained NDMA or NDEA? 6 A. I have an opinion related to that later 7 in my report, where I talk about the evidence that I 8 have seen indicates that it is not present in Diovan, 9 and I have not seen evidence to indicate that the -- 10 the opposite. Do you need me to tell you where I say 11 this or -- 12 Q. No, I don't. If Diovan, if some of the 13 Diovan manufactured by Novartis had trace amounts of 14 NDMA or NDEA, would that change your opinion that 15 ZHP's Valsartan is adulterated? 16 MR. VAUGHN: Objection. 17 A. I don't think it would change my opinion 18 that I would deem them adulterated because the 19 presence of those particular compounds, as the FDA 20 concluded, was that they were adulterated. And the 21 fact that they were being produced outside of good 22 GMP on top of the presence of those impurities would, 23 by the definitions, the regulatory definitions, deem 24 them adulterated. That's in my report as well. 25 Q. Did you undertake any investigation as</p>	<p style="text-align: right;">Page 125</p> <p>1 MR. VAUGHN: Hey, Jessica -- sorry, 2 Dr. Plunkett. 3 A. I'm citing to the Health Canada. I have 4 seen no document that indicates that Diovan had the 5 same problem as the API that was made by ZHP, sold 6 under ANDAs by ZHP companies for Teva or Torrent. 7 MR. VAUGHN: Jessica, I know you're on a 8 schedule. What time do you want to do lunch? 9 MS. MILLER: 1 o'clock, four minutes. 10 Q. Dr. Plunkett, in preparing your report, 11 did you speak to anyone who worked at ZHP? 12 A. No, I've read deposition testimony but 13 did not speak. 14 Q. Did you speak to anybody at the FDA? 15 A. No, I've not -- well, I've not spoken to 16 anyone at the FDA. I think what you mean is, having 17 to do with this particular project, no, I have not. 18 Q. In preparing your report, did you speak 19 to anybody who consulted with ZHP? 20 A. I don't believe, no. Some of the people 21 that I know wrote reports. I've not spoken to any of 22 them. 23 Q. And you did not speak to any organic 24 chemists in preparing your report either, did you? 25 A. No.</p>

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<p style="text-align: right;">Page 126</p> <p>1 Q. Who put together the documents that you 2 reviewed in this litigation?</p> <p>3 A. Oh, I do, as I typically do, I ask for 4 documents. Once we had a discussion of what areas 5 the attorneys were looking for me to address, which 6 is general toxicology and general regulatory 7 responsibilities, I then asked for certain kinds of 8 documents.</p> <p>9 I also asked them to send me certain 10 kinds of deposition testimony that might be related 11 to my opinions and then I asked for the expert report 12 of the chemist in the case. That was provided. 13 Plaintiff's expert. And then, as I always say to 14 them, "Certainly, please send me, if you get them, 15 defense experts that cover the same area I do." That 16 didn't come, however, until after my report was 17 drafted. Those were made available to my around the 18 23rd of December or 21st of December or something 19 like that.</p> <p>20 Q. Do you have confidence that you reviewed 21 all the documents that are relevant to your opinion?</p> <p>22 MR. VAUGHN: Object to form.</p> <p>23 A. I have confidence that I have reviewed 24 sufficient evidence to form and reach the con -- all 25 my opinions and reach the conclusions I have drawn.</p>	<p style="text-align: right;">Page 128</p> <p>1 listings to include all the documents reviewed after 2 submitting your report?</p> <p>3 A. The attorney -- Mr. Vaughn, I asked him 4 to provide that as part of your notice of deposition. 5 He did do that.</p> <p>6 Q. Did you go into any databases on your 7 own to search to documents that might be relevant to 8 your opinions?</p> <p>9 A. Are you asking for confidential 10 documents or for publicly-available documents? 11 Publicly available, certainly I did. I did my own 12 literature searches and I looked at the FDA website. 13 I looked at the FDA website for any type of 14 information that I could -- I could get to that was 15 related to my opinion.</p> <p>16 (Continued on following page.)</p>
<p style="text-align: right;">Page 127</p> <p>1 Q. Do you read Chinese?</p> <p>2 A. No, I do not.</p> <p>3 Q. Were all the documents in this 4 litigation written in English?</p> <p>5 A. No. But the documents that I have 6 reviewed and relied upon that were not in English had 7 English translations that were provided to me that, 8 as is typical in litigation. This isn't the first 9 litigation I've worked in that has had translated 10 documents.</p> <p>11 Q. Do you know whether all the documents 12 that were important to you forming your opinion have 13 been translated into English?</p> <p>14 MR. VAUGHN: Object to form.</p> <p>15 A. Any document that I've ever reviewed and 16 relied upon I had an English translation for. So 17 that's the only way I can that question. And I would 18 also indicate, I actually, when -- one thing I did 19 do, this is not in my report obviously because it was 20 after, one of the things I did do was, I looked at 21 what may or may not have been described within 22 reports of other experts in the case to -- but I 23 didn't see anything that would have changed my 24 opinion.</p> <p>25 Q. Have you prepared supplemental reliance</p>	<p style="text-align: right;">Page 129</p> <p>1 You're asking about confidential 2 documents, I asked those to be provided to me in 3 certain areas, but I did not search the database on 4 my own, no. It's apparently very, very large, from 5 what I understand.</p> <p>6 MR. VAUGHN: Ready for a break, Jessica?</p> <p>7 MS. MILLER: Sure.</p> <p>8 MR. VAUGHN: Great.</p> <p>9 VIDEOGRAPHER: Going off the record. 10 The time is 1:00 p.m. This is the end of media unit 11 2.</p> <p>12 (Luncheon recess: 1:00 p.m.)</p>

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<p style="text-align: right;">Page 130</p> <p>1 AFTERNOON SESSION 2 (1:43 p.m.) 3 L A U R A P L U N K E T T , having been 4 previously sworn, resumed the stand and 5 testified further as follows: 6 VIDEOGRAPHER: We're back on the 7 record. The time is 1:43 p.m. Eastern Time. This is 8 the beginning of media unit 3. 9 EXAMINATION (Cont'd.) 10 BY MS. MILLER: 11 Q. Dr. Plunkett, does a generic drug have 12 to have the same exact impurity profile as the 13 reference listed drug? 14 A. It has to have the same impurity profile 15 per the monograph, which would be the Reference 16 Listed Drug, yes. You would expect it to have the 17 same impurity profile as listed in the compendium. 18 Q. When you say the monograph, do you mean 19 the USP? 20 A. Yes, exactly. 21 Q. And did the USP monograph for Valsartan 22 require the identification of impurities over .1 23 percent? 24 A. At the time that the ANDAs were approved 25 in this case, no, but there's a separate issue in</p>	<p style="text-align: right;">Page 132</p> <p>1 drugs, but there may be in the guidance documents a 2 need to understand that some drugs may have different 3 issues addressed and the guidance will help you with 4 that. 5 Q. Do FDA guidance documents establish 6 legally enforceable responsibilities? 7 A. I'm not a lawyer, but based upon the 8 discussion in the documents themselves, there's 9 always a disclaimer statement, I guess, on the front 10 of most FDA guidance documents where they talk about 11 things not being legally binding; however, when you 12 read the documents, they also talk about some of the 13 guidance statements having directions such as "shall" 14 versus "can," and so there are some statements in the 15 guidance documents that are expectations in terms of 16 what would be complied with. 17 So in my experience, guidance documents, 18 since regulations are a minimum set of standards, 19 guidance set out some additional standards that the 20 FDA expects to be used when developing quality 21 systems our compliance programs within companies. 22 Q. Has the FDA stated that guidance 23 documents shall only be viewed as recommendations? 24 A. That's what I just told you. There's a 25 disclaimer in the front that, if you read further</p>
<p style="text-align: right;">Page 131</p> <p>1 which it has to do with, you would need to identify 2 things that were below .1 percent, based on your 3 chemical process assessment, if they were potent 4 toxicants or genotoxic. 5 Q. So where does it say that? 6 A. That is in the guidance information that 7 I cite in my report where I talk about the -- want me 8 to try to find it for you? Or, it's in my report, I 9 know I discussed this. 10 Q. You said it's in the guidance document, 11 right? 12 A. Yes, that's correct. 13 Q. What's a guidance document? 14 A. Guidance document is a document with 15 a -- depending on who it is. So let's say, either 16 USP or FDA, because FDA adopts USP standards and 17 guidance in many cases. It's a document that sets 18 forth the current thinking of the regulatory 19 authority on what standards or rules should be 20 applied in a particular situation, and also sets 21 forth and tries to answer often questions that have 22 been raised in their experience to give examples and 23 nor specific information, because the regulations are 24 often broad, not specific, right? The regulation is 25 broad to, for example, GMP for all human prescription</p>	<p style="text-align: right;">Page 133</p> <p>1 into almost every guidance document in the 2 introduction section, it also talks about, besides 3 that disclaimer, it also talks about the language 4 that may be chosen to be used in the guidance 5 document. 6 I'll also point out, based on my 7 experience and training, that one of the reasons that 8 guidance documents may not become final rules or 9 actually be set into regulations is because of the 10 recognition of how long it takes to get those things 11 there. So many times, guidance documents are issued 12 because it's FDA's quickest and fastest way to get 13 their thinking out to industry on what they would 14 like to see. 15 Q. Has the FDA stated that the use of the 16 word "should" in agency guidance means that something 17 is suggested, recommended, not that it is required? 18 A. That could be the -- I don't know if 19 it's exact language, but there's something similar to 20 that, yes, in there, yes. And -- well, not in -- I 21 don't know about every guidance document, but in many 22 of the ones that are issued here, yes, that's 23 correct. 24 Q. So do you agree that when the FDA uses 25 the term "should," that's not establishing a duty,</p>

34 (Pages 130 - 133)

<p style="text-align: right;">Page 134</p> <p>1 it's just establishing a recommendation?</p> <p>2 A. It's different. So I would agree with</p> <p>3 you that it's establishing a recommendation, but duty</p> <p>4 is different. So manufacturers have a duty to insure</p> <p>5 at all times during the life cycle of their product</p> <p>6 that it's safe and effective for the use as</p> <p>7 indicated. As a result, the manufacturers have a</p> <p>8 duty to do what they need to do to make sure that's</p> <p>9 the case.</p> <p>10 So I wouldn't use "duty" in that</p> <p>11 language. I would say, I would agree with you that</p> <p>12 they -- that you made a comment about it being a</p> <p>13 recommendation, but earlier on you told me you were</p> <p>14 not talking about responsibilities or duties.</p> <p>15 Well, the guidance documents set forth a</p> <p>16 little more than the minimum, but there is a separate</p> <p>17 duty that each manufacturer has, things they need to</p> <p>18 do and it's industry practice in my view, and the</p> <p>19 companies I've worked with, is, they typically do</p> <p>20 what is in the guidance documents when specific</p> <p>21 guidance is given on an issue.</p> <p>22 Q. Just to make sure I understand, because</p> <p>23 I'm not sure I understand your testimony, is it your</p> <p>24 testimony that the FDA guidance imposes duties on</p> <p>25 manufacturers?</p>	<p style="text-align: right;">Page 136</p> <p>1 that's how I'm using that word. So they have a duty.</p> <p>2 Now, the law, you're right, the law has</p> <p>3 some very specific duties that are laid out, and one</p> <p>4 of those is the one I started with, which is, it's</p> <p>5 the duty of the manufacturer to ensure that the</p> <p>6 product is, remains safe and effective throughout its</p> <p>7 life cycle for its intended use. It's not FDA's</p> <p>8 responsibility or duty, it's theirs.</p> <p>9 So the company, those regulations and</p> <p>10 the standards and all of the things that we're</p> <p>11 talking about are things that the company needs to be</p> <p>12 doing, because it's not -- FDA isn't the one that is</p> <p>13 manufacturing the drug. FDA is not the one that's</p> <p>14 selling the drug. FDA is not the one that's making</p> <p>15 the profits off the drug. It's the company. So they</p> <p>16 have a set of duties because of that role that they</p> <p>17 play.</p> <p>18 Q. Where is that duty codified?</p> <p>19 A. That's looking at every responsibility</p> <p>20 set forth in the FDA regulations. If you go back to</p> <p>21 Section 200 throughout, 300, 400, sections, it's</p> <p>22 21 CFR, and look at what is the responsibility of a</p> <p>23 manufacturer. A manufacturer is the one that has to</p> <p>24 do this. The manufacturer is the one that has to do</p> <p>25 that. And then if you go to some of the general</p>
<p style="text-align: right;">Page 135</p> <p>1 A. The guidance impose -- no, I said the</p> <p>2 guidance imposes a -- it's FDA's thinking or their</p> <p>3 recommendations. Now, if they use the word "shall"</p> <p>4 in a document, that's different. That's something</p> <p>5 they are saying will be done, right? But when they</p> <p>6 use the word "should," you're exactly right, it's</p> <p>7 part of the recommendations.</p> <p>8 But then I said to you, based on my</p> <p>9 training and experience, working with industry and</p> <p>10 complying with guidance documents, industry,</p> <p>11 responsible manufacturers will take that information</p> <p>12 and use it as their standards that they will apply --</p> <p>13 more specific standards they will apply as part of</p> <p>14 compliance with the general regulation in that area,</p> <p>15 if it relates to them. I mean, there may be a</p> <p>16 guidance issue that doesn't relate to that particular</p> <p>17 company and if it does, it's my experience that they</p> <p>18 would use that guidance and attempt to comply with</p> <p>19 it, if they can.</p> <p>20 Q. Are you using the term "duty"</p> <p>21 differently from "legally enforceable</p> <p>22 responsibility"?</p> <p>23 A. I'm using "duty" -- I'm not a lawyer so</p> <p>24 I'm using "duty" -- their duty as a responsible</p> <p>25 manufacturer based on my training and experience, so</p>	<p style="text-align: right;">Page 137</p> <p>1 statements at FDA's website, and if you need to</p> <p>2 explore a specific site I'll have to go find it,</p> <p>3 but there's general statements on what is the</p> <p>4 responsibility of a drug manufacturer, and they talk</p> <p>5 about those specific things that they must do. It's</p> <p>6 their responsibility to do testing, it's their</p> <p>7 responsibility to put together the application. It's</p> <p>8 their responsibility to have post-market surveillance</p> <p>9 in place, it's their responsible to have a quality</p> <p>10 management system in place. All of those things are</p> <p>11 in the regulations linked with the manufacturer, not</p> <p>12 with the FDA.</p> <p>13 Q. Have you read the MSP complaint?</p> <p>14 A. I don't know what you're referring to.</p> <p>15 Q. Have you read the complaint in this</p> <p>16 case?</p> <p>17 A. If it was on my reliance materials, I</p> <p>18 may have looked at it, I'm not sure. Can you tell</p> <p>19 me -- let me look, I have my appendix C. Hold on.</p> <p>20 If I have, it's been a while, I don't know.</p> <p>21 Q. Do you remember reading the complaint in</p> <p>22 this case?</p> <p>23 A. I have no specific memory. I often do,</p> <p>24 though, that's why I'm saying that. So let me look</p> <p>25 and see if you want -- if you want a specific answer,</p>

<p style="text-align: right;">Page 138</p> <p>1 if it's in my reliance list, I have.</p> <p>2 Q. Okay. So your reliance list, maybe this</p> <p>3 will be helpful, your reliance list is appendix C,</p> <p>4 and it's one, two, three, four, it's four-and-a-half</p> <p>5 pages, double columns.</p> <p>6 Did you read every single document</p> <p>7 that's listed there?</p> <p>8 A. Yes, I have looked at every single</p> <p>9 document that's in here, yes, at some point in time.</p> <p>10 That's why it's listed. Many of -- let me just say,</p> <p>11 many of these documents are -- were Bates-numbered</p> <p>12 exhibits to deposition testimony as well.</p> <p>13 Q. And what's the difference between</p> <p>14 "looked" and "read"? I just want to make sure I</p> <p>15 understand. I asked, did you read, and you said, "I</p> <p>16 have looked."</p> <p>17 A. I have -- look, every document here has</p> <p>18 been opened up, I may have read it, I may have</p> <p>19 skimmed and read some more thoroughly, it depends.</p> <p>20 For example, on some of the deposition testimony, I</p> <p>21 may not have read every word but I certainly skimmed</p> <p>22 through the entire deposition and I compared the</p> <p>23 exhibits, to look at the exhibits, to see if they are</p> <p>24 relevant to my area of expertise because there were</p> <p>25 some depositions that some of the information that</p>	<p style="text-align: right;">Page 140</p> <p>1 a Quality Management System that isn't adequate, and</p> <p>2 you can have a Quality Management System that is</p> <p>3 robust.</p> <p>4 Q. Are you offering an opinion that the</p> <p>5 Quality Management System was not adequate?</p> <p>6 A. That was beyond the scope. Dr. Bain, I</p> <p>7 believe, is addressing those specific issues in terms</p> <p>8 of the case. Maybe also someone else, but I've read</p> <p>9 Dr. Bain's report and I know she addresses that to</p> <p>10 some extent.</p> <p>11 Q. Did you speak to Dr. Bain?</p> <p>12 A. No, I haven't spoken to any of the -- to</p> <p>13 short-circuit it, I haven't spoken to any of the</p> <p>14 experts on either side much this case.</p> <p>15 Q. Were you familiar with Dr. Bain before</p> <p>16 you got involved in this litigation?</p> <p>17 A. No I was not familiar with her.</p> <p>18 Q. Were you familiar with Dr. Hecht before</p> <p>19 you got involved in this litigation?</p> <p>20 A. No, I was not.</p> <p>21 Q. You mentioned the warning letters,</p> <p>22 correct?</p> <p>23 A. Yes, I have.</p> <p>24 Q. What's a warning letter?</p> <p>25 A. A warning letter is a administrative</p>
<p style="text-align: right;">Page 139</p> <p>1 was being discussed was beyond the scope of the</p> <p>2 opinions I was forming. But I would -- all of these</p> <p>3 documents would be fair game if you want to go and</p> <p>4 look at one, and I can tell you my opinion, how it</p> <p>5 does or doesn't support my opinion, or what it was --</p> <p>6 what it is or is not relevant to.</p> <p>7 Q. Are you offering an opinion in this case</p> <p>8 as to the conditions that are necessary for DMF to</p> <p>9 degrade?</p> <p>10 A. No. I believe that's what the chemist</p> <p>11 is doing. I cite to the fact that -- I think I talk</p> <p>12 about what the different processes were, and I point</p> <p>13 out some of the observations about what the agency,</p> <p>14 FDA even identified was there, or the company was</p> <p>15 aware of was there, based on deposition testimony.</p> <p>16 But I have not done an independent analysis. That</p> <p>17 would be what the chemist has done in terms of</p> <p>18 foreseeability.</p> <p>19 Q. Does ZHP have Quality Management Systems</p> <p>20 in place, QMS?</p> <p>21 A. Well, they supposedly did, based upon</p> <p>22 the documents I've seen, but this is one of the</p> <p>23 things that they got cited for in terms of their FDA</p> <p>24 warning letter on the inadequacies of some of their</p> <p>25 Quality Management System issues. So you could have</p>	<p style="text-align: right;">Page 141</p> <p>1 action that can be taken. It's a tool that the FDA</p> <p>2 uses once they have had an inspection, typically for</p> <p>3 example, of a facility. And if the inspection has</p> <p>4 identified regulatory compliance issues that are</p> <p>5 significant, the FDA will send a warning letter.</p> <p>6 Sometimes the warning letter doesn't come</p> <p>7 immediately, sometimes they have a -- a untitled</p> <p>8 letter or a discussion that they have with the</p> <p>9 company to try to achieve compliance or solve</p> <p>10 compliance concerns. And if -- but if those things</p> <p>11 don't happen, then another warning letter can follow</p> <p>12 as well around the things that weren't resolved.</p> <p>13 But it is an action that must be</p> <p>14 responded to, so I think it's 15 days, basically 15</p> <p>15 days after receiving a warning letter to respond to</p> <p>16 the agency with something, saying that, you know,</p> <p>17 what they are planning on doing or -- they -- I've</p> <p>18 helped companies in the past respond to warning</p> <p>19 letters.</p> <p>20 For example, sometimes the response is,</p> <p>21 "We have engaged with a consultant who is going to be</p> <p>22 coming to our facility on XYZ," or, "We've engaged an</p> <p>23 attorney that will be assisting us with changing or</p> <p>24 revisiting some of these issues and then we'll get</p> <p>25 back to you," and then the FDA expects a follow-up.</p>

<p style="text-align: right;">Page 142</p> <p>1 Q. Has the FDA stated that warning letters 2 are informal and advisory? 3 A. Yes. They -- well, I know they are 4 informal, but to me an entitled letter is what I 5 would call informal. It's possible that FDA said 6 that, but when I talk with my clients, I talk about a 7 warning letter as being something that's serious and 8 has to be addressed, because there's a time issue 9 with it. 10 But there's advisories. They are 11 telling the company what problems exist that need to 12 be addressed, so in that case, yes. And in that 13 case, it's not an enforcement action such as a recall 14 or a banning or a criminal, you know initiation of 15 criminal procedures, a lot of different things that 16 could happen. It's not an import alert, which is a 17 more formal action that should be taken. 18 Q. Are you familiar with the FDA regulation 19 or procedures manual? 20 A. Yes generally, yes. Some sections more 21 familiar than others. 22 Q. Do you know whether that manual refers 23 to warning letters as informal and advisory? 24 A. I'd have to go back and look. I don't 25 recall any of the specific language in it.</p>	<p style="text-align: right;">Page 144</p> <p>1 Q. Is it fair to say that a warning letter 2 is issued to achieve voluntary compliance? 3 A. Yes, that's the -- FDA is always using a 4 carrot rather than a stick first, unless there is 5 something very, very serious that has risen to a 6 level of criminal, in which case the stick may come 7 right out. 8 Q. And if you undertake corrective action, 9 the FDA can close out a warning letter, right? 10 A. Yes, that's what it said, that's typical 11 of the actions that can happen, so that would mean a 12 finalization of the process for that particular issue 13 raised in that warning letter. 14 Q. Do you know if the FDA closes out a 15 warning letter, what does it mean? 16 A. It means that for the issues raised in 17 that warning letter, there has been some action or 18 information provided to -- that makes that warning 19 letter issue either moot or has been resolved. So 20 for example, you could make the issue in the warning 21 letter moot if you said, "I'm just going to stop 22 making the drug." You may, however, say, "We're 23 going to put these processes in place, we're going to 24 be putting in testing," to ensure, for example, like 25 in this case, companies are expected to show that</p>
<p style="text-align: right;">Page 143</p> <p>1 Q. Is a warning letter considered final 2 agency action? 3 A. No. Again, it requires a response. So 4 that could lead to formal -- typically in my 5 experience, a warning letter gets responded to and 6 then the agency, the FDA will respond to your 7 response with a closure of an action or, you know, 8 indicate that additional -- additional work may be 9 needed. 10 Q. The FDA expressly has stated that 11 warning letters are not final and binding, right? 12 A. Well, obviously they are not final 13 because follow-up is expected. I don't know what you 14 mean by "binding." If what -- by binding, what they 15 are meaning is that you can make an alternative 16 argument and they will consider it, that is true. In 17 other words, what the findings are in a warning 18 letter may change or the opinion of the agency could 19 change depending on the information and arguments 20 presented by the affected party, if that's what 21 they're saying. 22 Q. Fair to say -- 23 A. Again, if you're referring to the 24 regulatory procedure manual, then I'd have to look, I 25 don't know, that is fair.</p>	<p style="text-align: right;">Page 145</p> <p>1 will there is no NDMA or NDEA or nitrosamines present 2 before they release product, those kind of things. 3 Q. Are you offering an opinion that ZHP's 4 QMS was inadequate? 5 A. You already asked me that, and I said 6 that was beyond the scope. That's something that 7 Dr. Bain, I believe, is addressing. 8 Q. So if that's the case, if it's beyond 9 the scope, why do you mention QMS in your report? 10 A. To give context to why, what companies 11 are required to do, because I talk about 12 responsibilities, overall responsibilities of what a 13 drug manufacturer is supposed to do, and I also talk 14 about limitations of the FDA. And those are both 15 important context opinions or -- not opinions, 16 context to give when I talk about different issues in 17 the case. 18 And I was asked in this case to provide 19 a general overview of some of the important 20 regulatory issues that the company would need to 21 address, things they have to have in place, or things 22 they should be doing in order to be manufacturing the 23 drugs in compliance with, generally with FDA 24 regulation. 25 Q. Other than the fact that you have</p>

<p style="text-align: right;">Page 146</p> <p>1 testified already today that ZHP did not conduct, in 2 your opinion, an adequate risk assessment, do you 3 have any other opinions as to things that you believe 4 ZHP did that were contrary to FDA regulation? 5 A. Well, several times in my report I say 6 that they put patient health at risk because of the 7 actions they took. They are not doing -- not doing 8 the risk assessment, for example, to understand that 9 they were selling a product, or marketing a product 10 that had these toxic contaminants -- toxic 11 impurities, carcinogens in them. I'll look, I mean, 12 I have a couple of -- I have a summary -- I have a 13 summary opinion -- 14 Q. No, no. 15 A. -- at page -- 16 Q. I don't think you're understanding my 17 question. Other than the risk assessment 18 requirement, are there any specific FDA regulations 19 that you are saying ZHP did not comply with? 20 A. I don't think I state my opinion the way 21 you're stating it. But I certainly do think some of 22 my opinions are relevant to the question you're 23 asking. I don't know how else to answer it. So 24 you'll notice in my report, I think you'll notice in 25 my report that you don't see a number of statements</p>	<p style="text-align: right;">Page 148</p> <p>1 quotations, and some of those are out of regulations, 2 some of those are out of the statute itself, so I 3 know I address that as well, the issue of the fact 4 that the drugs, the Valsartan products that contain 5 NDEA and NDMA would be deemed adulterated; and as a 6 result of that, they would not be pharmaceutically 7 equivalent, and by the definition of "bioequivalent 8 drugs," which have to be therapeutically equivalent 9 and pharmaceutically equivalent, that would be an 10 issue that I'm raising in terms of the regulations. 11 But it's -- I don't know how else to 12 answer for you. I'd say that I was very -- I was 13 very -- "careful" is not the right word, but I tried 14 to be very specific and direct in my language I use 15 so you understand what I am saying, and if I -- I 16 typically, since Dr. Bain is the one, and others, 17 that are doing GMP compliance, many of the regulatory 18 issues that you would point to from these standards 19 or parts of the 21 CFR that they are handling, and I 20 did not do that. 21 Q. Is there a place in FDA regulations 22 where it says bioequivalence means that you have the 23 exact same impurity profile? 24 A. Well, let me -- there is a statement 25 about purity. So hold on.</p>
<p style="text-align: right;">Page 147</p> <p>1 that say, "They violated this regulation," or, "They 2 violated that regulation." Because that analysis was 3 being done by, in my -- the information was given in 4 the reports I've seen by other experts. 5 Instead, what I have provided, I 6 believe, in my report, is, I have talked about what 7 are the responsibilities of a manufacturer under the 8 regulations, what regulations apply to them, and what 9 issues I see. 10 And I see issues with the improper risk 11 assessment, for example, which leads to them 12 producing a product that I believe would be deemed 13 adulterated. So I guess what I'm saying, it's being 14 deemed adulterated, that's a violation of the -- of 15 the regulations that deal with adulteration of 16 products under the -- under both the law itself, 17 section 351 CFR; and also other parts of the -- the 18 quality regulations that talks about the need to 19 produce a product that is -- that is not adulterated. 20 Q. Are there any other regulations sitting 21 here today that you believe ZHP violated? 22 A. I believe they sold -- they sold a 23 product that I believe was not pharmaceutically 24 equivalent. So part of the regulations -- I mean, I 25 give you sections -- I pull out certain sections and</p>	<p style="text-align: right;">Page 149</p> <p>1 (A pause in the proceedings.) 2 A. So paragraph 21, under the definitions 3 of what is a pharmaceutical equivalent, and that 4 comes from FDA's own regulations, "Pharmaceutical 5 Equivalence," and goes on, goes up halfway down, and 6 it says, "And meet the identical compendial or other 7 applicable standard of identity, strength, quality 8 and purity," and the purity is the issue, as it 9 states here. 10 They were making Valsartan in ZHP, and I 11 don't have any evidence to indicate their Valsartan 12 tablets weren't of the claimed strength, but I have 13 evidence to indicate that the Valsartan tablets had a 14 different purity profile than the Reference Listed 15 Drug, in the presence of the NDMA and the NDEA, and 16 the lack of investigation they did to understand the 17 chemical process. 18 Q. Does this sentence say that the two 19 drugs have to have the same purity or does it say 20 that the drawing must meet the identical compendial 21 on other applicable standard of identity? 22 MR. VAUGHN: What page were you on of 23 her report? I'm sorry. 24 MS. MILLER: We're on paragraph 21. 25 THE WITNESS: She had read the language</p>

<p style="text-align: right;">Page 150</p> <p>1 to me.</p> <p>2 MR. VAUGHN: I got lost.</p> <p>3 A. Go back to the original question,</p> <p>4 though, because I thought what I was answering for</p> <p>5 you was what you were asking. So what is your</p> <p>6 question now? Say your question again, because maybe</p> <p>7 I misheard your question. I thought I was pointing</p> <p>8 to this because I thought this answered your question</p> <p>9 directly.</p> <p>10 Q. Does a generic drug have to have the</p> <p>11 exact same impurity profile as the RLD?</p> <p>12 MR. VAUGHN: Objection, vague.</p> <p>13 A. So that was why I went here. So in</p> <p>14 order to be a generic -- in order for a generic drug</p> <p>15 to be legally marketed, it has to be bioequivalent.</p> <p>16 And "bioequivalent" includes two parts. It's the</p> <p>17 therapeutic equivalence; but it's also, as set forth</p> <p>18 here, the pharmaceutical equivalent. And I'm saying</p> <p>19 to you that if they are comparing themselves, which</p> <p>20 they are, they -- when I say "they," ZHP is making a</p> <p>21 product where their RLD is supposedly Diovan, and</p> <p>22 they use the monograph as a standard for that, and</p> <p>23 then they change the process, that they don't believe</p> <p>24 that that process is making any "significant changes"</p> <p>25 such that they would expect something different, but</p>	<p style="text-align: right;">Page 152</p> <p>1 there to be a listing for that in the monograph and</p> <p>2 it's not there. Instead, what happens is, that drug</p> <p>3 in the monograph, made by the TIN process, was not</p> <p>4 anticipated or expected to make NDMA or NDEA.</p> <p>5 When they changed the process, this is</p> <p>6 when ZHP becomes responsible for making sure that</p> <p>7 their changes to the process don't change the profile</p> <p>8 as they compare it back to the standard, and I'm</p> <p>9 saying to you, that's the problem here. They</p> <p>10 didn't -- because of not doing their, as they admit</p> <p>11 in their deposition testimony that they didn't do,</p> <p>12 and there are stipulations that they made that they</p> <p>13 didn't do a complete review of their process, and yet</p> <p>14 there's also discussion among -- of the fact that ZHP</p> <p>15 employees were aware that, in 2017, at least, that</p> <p>16 their process could produce genotoxins like NDMA. So</p> <p>17 that's what I'm pointing to. That's the evidence I'm</p> <p>18 pointing to, the paragraphs that describe it.</p> <p>19 There's additional description of that</p> <p>20 issue I was bringing up about what the company knew</p> <p>21 in other parts of my report, and I can find it for</p> <p>22 you if you need me to.</p> <p>23 Q. Where can I find everything you just</p> <p>24 said in the USP monograph?</p> <p>25 A. Everything I just said is -- I don't</p>
<p style="text-align: right;">Page 151</p> <p>1 yet they don't investigate it. The fact that they</p> <p>2 then signed that they are making NDEA and NDMA, makes</p> <p>3 the purity of their drug different from the Reference</p> <p>4 Listed Drug, and I don't know how, more specific way</p> <p>5 to say it. I have it there, and I have other --</p> <p>6 paragraph 22 I talk about it as well.</p> <p>7 Q. You're not answering my question. My</p> <p>8 question is, what was the compendial and/or other</p> <p>9 applicable standard of identity?</p> <p>10 A. You have to go to the USP monograph for</p> <p>11 Diovan for the Record Listed Drug, and we've already</p> <p>12 discussed this --</p> <p>13 MR. VAUGHN: Let her finish her answer.</p> <p>14 A. -- and we already discussed this,</p> <p>15 because you're asking specific questions about the</p> <p>16 compendial standard, and I think you mentioned .1</p> <p>17 percent, .1 percent are the compendial standards,</p> <p>18 don't mention NDMA and NDEA. However, it doesn't</p> <p>19 mean that you ignore what you're supposed to do in</p> <p>20 order to make sure that what you're doing is making a</p> <p>21 product that doesn't have something that is not</p> <p>22 listed.</p> <p>23 So for example, if the monograph had</p> <p>24 been approved such that NDMA was going to be allowed</p> <p>25 as a potent toxicant or genotoxicant, I would expect</p>	<p style="text-align: right;">Page 153</p> <p>1 understand. Some of what I just said to you is my</p> <p>2 opinion based on the evidence that exists. Are you</p> <p>3 asking me -- what are you asking me? What,</p> <p>4 everything that I just said? Because I did say a</p> <p>5 lot, I apologize.</p> <p>6 Q. The USP monograph simply says not more</p> <p>7 than 0.1 percent of any other individual impurity,</p> <p>8 correct?</p> <p>9 A. Yes, but there's also -- there is also</p> <p>10 the understanding with these monographs, when you go</p> <p>11 to the USP website and also to the ICH guidance that</p> <p>12 goes along with all of these issues, that that</p> <p>13 statement for .1 percent does not apply to potent</p> <p>14 toxicants or genotoxins.</p> <p>15 Q. Can you show me where it says that?</p> <p>16 A. In my report --</p> <p>17 Q. No, not in your report. Where it says</p> <p>18 that in USP. Where does it say in USP that the term</p> <p>19 "any other individual impurity" does not actually</p> <p>20 mean "any other individual impurity"?</p> <p>21 A. I don't understand your question. I'm</p> <p>22 telling you --</p> <p>23 Q. It says here, "Any other individual</p> <p>24 impurity," that's the language in USP, and you're</p> <p>25 saying that's not what it actually means. Where can</p>

<p style="text-align: right;">Page 154</p> <p>1 I go to USP to see that actually the term "any other 2 individual impurity" has a caveat, the caveat you 3 just referenced?</p> <p>4 A. It would be the information that goes 5 along with the implementation of the monograph. So 6 it would be going back to the general -- there's 7 general procedures, or general chapters USP cites 8 that talk about impurities. So you go there, and you 9 look at what they describe as far as impurities, and 10 then you go to the ICH documents that talk about the 11 monographs and the development of impurities. So 12 that you can't look at just the USP monograph, you 13 shouldn't be looking at the USP monograph in 14 isolation from the other information that talks about 15 how to use that monograph, is what I'm telling you.</p> <p>16 The company in this case, 17 "company" being ZHP, and then also Teva and Torrent, 18 because they accepted what ZHP supposedly did, the 19 issue is that they were making a product where they 20 didn't have control of their process, and by not 21 having control in terms of knowing what their process 22 was doing, they were making something that had a 23 genotoxin in it, and as a result that .1 percent any 24 other impurity, based upon the complete evidence of 25 how these monographs are developed and used, is</p>	<p style="text-align: right;">Page 156</p> <p>1 stipulate that they didn't do it, and I don't -- I 2 have no evidence to show that they ever told FDA, 3 "Oh, by the way, we didn't do that." In fact -- in 4 fact, what they did tell FDA and the people they 5 supplied to, they actually say that there were no 6 genotoxic byproducts or degradants in the process, 7 and yet they had never done the work to figure out 8 whether they actually could be there.</p> <p>9 Q. Are you of the opinion that the FDA's 10 limitation of resources somehow affected patient 11 safety here?</p> <p>12 A. I don't think I form the opinion that at 13 any particular case it's effected patient safety. 14 But the limitations of the FDA are an important 15 context for why it is that it's the company that is 16 responsible for doing all the work, what you were 17 rating out that the FDA may have called "hard." It's 18 not hard work if you do the work, and that's the 19 point.</p> <p>20 You have to do the work, take the time, 21 go through the process, understand your process, and 22 make sure that what you're selling is going to be 23 safe and will not put patient health at risk.</p> <p>24 Q. Do you know how many times the FDA 25 inspected the ZHP facility during the time period at</p>
<p style="text-align: right;">Page 155</p> <p>1 inconsistent, and that's what I'm telling you --</p> <p>2 Q. You keep answering questions I'm not 3 asking. My question is very simple. Where in USP, 4 where, what book in USP can I go to, to find a 5 statement that "any other individual impurity" does 6 not apply in this circumstance?</p> <p>7 A. I thought I just tried to tell you that. 8 I said to go through the general chapters on 9 impurities where they discuss impurities. And then I 10 also told you to go to the guidance documents put up 11 by ICH which talk about implementation of some of 12 these things.</p> <p>13 Q. And that's --</p> <p>14 A. I don't know what else to tell you. I 15 mean, I'm trying to answer your question consistent 16 with my experience but also, I mean, in my report, I 17 lay this out. Maybe let's go to my report, tell me 18 what it is that you don't agree with and I'll try to 19 explain it to you. Obviously you disagree with 20 something I've said in my report.</p> <p>21 Q. Is it your opinion that ZHP withheld any 22 safety information from FDA that it was aware of?</p> <p>23 A. Yes, it withheld the fact that it never 24 did a full evaluation of its chemical process. 25 That's important to patient safety. So they</p>	<p style="text-align: right;">Page 157</p> <p>1 issue in this litigation?</p> <p>2 MR. VAUGHN: Objection, foundation.</p> <p>3 A. Well, I don't even know all of the time 4 period. Can you tell me your time period? Maybe I 5 can tell you if you tell me what time period is at 6 issue.</p> <p>7 Q. Well, do you have an opinion as to what 8 the time period was when Valsartan was -- had 9 impurities of NDMA and NDEA?</p> <p>10 A. Well, we don't know the exact time 11 period. I would argue, based on the evidence that 12 I've seen, it goes back at least as far to 2014 in 13 terms of having a process that was in place that, 14 where they were seeing unidentified impurities. But 15 certainly whenever they started using either the -- 16 whenever they started using a process other than the 17 TIN process without doing the full evaluation of 18 their chemical process, that raises the issue of 19 potential contaminants that are nitrosamines.</p> <p>20 Q. Beginning at that point until the 21 product was recalled, how many times did the FDA 22 inspect ZHP facilities?</p> <p>23 A. I have -- don't have a count off the top 24 of my head. I can't tell you that. If you need to 25 know that, I imagine the number -- I could find that</p>

<p style="text-align: right;">Page 158</p> <p>1 in Dr. Bain's report, because I think she goes over 2 the inspections, or maybe it was not Dr. Bain, it may 3 have been Dr. Russ, maybe, I have to go look. 4 Q. Do you know how many of those 5 inspections resulted in regulatory action? 6 A. Again, I'd have to go look. That was 7 beyond the scope. I wasn't trying to count up how 8 many times. 9 Q. In fact, there were multiple FDA 10 inspections during that period, none of which 11 resulted in official regulatory action, isn't that 12 right? 13 A. Do you mean a warning letter, or are you 14 talking about a recall, what are you talking about? 15 Q. Any official regulatory action? 16 A. Well, they had more than one warning 17 letter during that period of time. And I did do a 18 search of the FDA website for that, looking for 19 warning letters. There's more than the one that came 20 out in 2019. But I can't give you an exact number. 21 I'd have to go back and look again at the rather 22 large database. 23 Q. Can you identify any warning letter 24 other than the 2019 warning letter that had to do 25 with Valsartan?</p>	<p style="text-align: right;">Page 160</p> <p>1 MS. MILLER: I know, but I need to take 2 a break. 3 MR. VAUGHN: I thought you were asking 4 us. 5 MS. MILLER: Thanks. 6 VIDEOGRAPHER: All right, going off the 7 record, the time is 2:23 p.m. Eastern Time, this is 8 the end of media unit 3. 9 (Recess taken.) 10 VIDEOGRAPHER: We're back on the record. 11 The time is 2:40 p.m. Eastern Time, this is the 12 beginning of media unit 4. 13 EXAMINATION (Cont'd.) 14 BY MS. MILLER: 15 Q. Dr. Plunkett, are you aware of any 16 monograph that references nitrosamine impurities? 17 A. In terms of an acceptable impurity, is 18 that what you're asking me? 19 Q. Are you aware of any USP monograph that 20 references nitrosamine impurities in any capacity 21 whatsoever? 22 A. I'm not aware of one where they are 23 considered an acceptable part of the specification in 24 the compendium, no. And in fact, if you go to the 25 USP website, they have, now, they have a section on</p>
<p style="text-align: right;">Page 159</p> <p>1 A. Well, warning letters that deal with 2 failure of quality systems or violations of CGMPs, 3 and the best one I'm thinking of, there was an older 4 letter that I believe they cited ZHP for a violation 5 of GMPs, that they were looking at the production of 6 a different drug, but if -- other than Valsartan, but 7 if you look at the way that the FDA writes the 8 letters, and I'd have to pull the letter back out, 9 but I believe that the statement they make is not 10 just, "You violated CGMPs for Valsartan or for 11 Losartan," or whatever drug, "You violated CGMPs and 12 you're making adulterated drug products." 13 Q. FDA never used the word "adulterated" 14 with respect to Valsartan until 2019, correct? 15 A. It did not deem it adulterated until 16 2019, that is true. However, if you read my report, 17 I talk a little bit about this. 18 Q. I read your report several times, 19 Doctor. 20 MS. MILLER: Do you want to take a 21 break? 22 THE WITNESS: I'm fine going forward, 23 it's up to you. 24 MR. VAUGHN: Going for like fifty 25 minutes, is it --</p>	<p style="text-align: right;">Page 161</p> <p>1 nitrosamines and pages that talk about how those are 2 unacceptable contaminants and -- or impurities and 3 have been problematic in the industry. 4 Q. Are you offering an opinion that 5 bioequivalence was lacking here because of the 6 preference of NDMA and NDEA impurities in the 7 Valsartan ZHP API? 8 A. Not exactly. Want me to explain what my 9 opinion is? 10 Q. That is not your opinion? 11 A. That's not the exact opinion. You're 12 not stating it quite as I would. Would you like me 13 to explain? It's in my report. Actually, I talked 14 about the issue of, bioequivalent means two things: 15 Therapeutically equivalent, and pharmaceutically 16 equivalent. And the pharmaceutically equivalent 17 piece that I believe the presence of the NDMA and the 18 NDEA affect the status of the drug as being 19 "bioequivalent," and FDA stated they are adulterated. 20 By being adulterated, they are not going 21 to be deemed to be bioequivalent, at least that lot, 22 even though the ANDA still exists, and then 23 bioequivalence -- bioequivalence termination has not 24 been rescinded by FDA. 25 Q. How is that different from what I just</p>

<p style="text-align: right;">Page 162</p> <p>1 said?</p> <p>2 A. Well, I mean, I'm being more precise and</p> <p>3 exacting. That's what I'm telling you. The</p> <p>4 bioequivalent -- the reason I'm doing this is because</p> <p>5 I have seen documents where people focus on</p> <p>6 bioequivalent as only on the therapeutic equivalence</p> <p>7 piece of the puzzle, and it's both.</p> <p>8 Q. Are you offering an opinion that</p> <p>9 pharmaceutical equivalence was lacking merely because</p> <p>10 the Valsartan API had NDMA and NDEA impurities?</p> <p>11 MR. VAUGHN: Object to form.</p> <p>12 A. Well, it's not merely because, it's an</p> <p>13 important -- it's important impurities. It is my</p> <p>14 opinion that they were not pharmaceutically</p> <p>15 equivalent when the process used to make them were</p> <p>16 being -- resulting in the presence of NDMA and NDEA,</p> <p>17 yes, that's correct, because those are the types of</p> <p>18 impurities that would not fit at the .1 percent based</p> <p>19 upon the USP.</p> <p>20 Q. Did Valsartan ever have NDMA or NDEA</p> <p>21 over 0.1 percent?</p> <p>22 A. I haven't done that evaluation. I can't</p> <p>23 answer that. But the .1 percent doesn't apply to</p> <p>24 genotoxins, so NDMA and NDEA would have a different</p> <p>25 issue to be -- that they would have to content with.</p>	<p style="text-align: right;">Page 164</p> <p>1 A. Well, they wouldn't have that statement</p> <p>2 this there. I doesn't make any sense. That's what</p> <p>3 I'm trying to tell you. I'm trying to tell you that</p> <p>4 the -- well, if you go for the general -- if you open</p> <p>5 the general chapter -- general chapters, and I don't</p> <p>6 know, 5.6, something like that, it's called</p> <p>7 "Impurities," "Substance Impurities," something like</p> <p>8 that in the general chapters, and it talks about what</p> <p>9 to do, and it talks about when you view the process</p> <p>10 that is not -- was not part of the original process</p> <p>11 by which the RLD was developed, that you have to look</p> <p>12 for and understand what impurities are possible. And</p> <p>13 then that, combined with the fact that genotoxic</p> <p>14 impurities are a separate issue in terms of how they</p> <p>15 are handled, that's what I'm pointing to.</p> <p>16 So there are potent toxicants,</p> <p>17 genotoxicants, there can be toxicants that weren't</p> <p>18 genotoxic that were potent enough that apply the .1</p> <p>19 percent standard.</p> <p>20 Q. Is there a page in any USP document that</p> <p>21 says when you are dealing with a potentially</p> <p>22 genotoxic impurity, you cannot have even less than .1</p> <p>23 percent of that impurity in your medication?</p> <p>24 MR. VAUGHN: Object to form.</p> <p>25 A. I can't tell you if that sentence that</p>
<p style="text-align: right;">Page 163</p> <p>1 If you wanted to make them listed impurities, that's</p> <p>2 a different issue.</p> <p>3 Q. If an impurity of less than 0.1 doesn't</p> <p>4 have to be identified, how is it possible that it</p> <p>5 doesn't apply to genotoxins? Is it your opinion that</p> <p>6 no unidentified impurity in any medication under 0.1</p> <p>7 percent is a genotoxin?</p> <p>8 MR. VAUGHN: Object to form.</p> <p>9 A. No. That's not at all what I'm saying.</p> <p>10 You're conflating things. So the issue here is,</p> <p>11 because the process was changed and the chemical</p> <p>12 analysis or the -- analysis of the chemical process</p> <p>13 did not look for the potential for genotoxic</p> <p>14 impurities to result, when those genotoxic impurities</p> <p>15 do result, that makes that particular product no</p> <p>16 longer pharmaceutically equivalent.</p> <p>17 The Diovan RLD process with the TIN had</p> <p>18 been shown to be able to be used to manufacture</p> <p>19 Diovan without the presence of NDMA or NDEA based on</p> <p>20 the Health Canada results, for example.</p> <p>21 Q. But you have not been able to point me</p> <p>22 to a page in the USP -- in any USP manual or document</p> <p>23 that says .1 or less of any other individual impurity</p> <p>24 excludes potential genotoxins, correct?</p> <p>25 MR. VAUGHN: Object for form.</p>	<p style="text-align: right;">Page 165</p> <p>1 you're reading is there, but I can tell you that if</p> <p>2 you read the general chapters of the USP, in</p> <p>3 combination with the guidance that exists, genotoxic</p> <p>4 impurities are segregated out as a special group or a</p> <p>5 special class that are considered differently, where</p> <p>6 the .1 percent may not be adequate in terms of</p> <p>7 protecting and making sure that the drug is safe.</p> <p>8 Q. All right. So now you're saying there's</p> <p>9 a place in USP that says .1 percent may not be</p> <p>10 adequate?</p> <p>11 A. The guidance documents talk about where</p> <p>12 these impurity standards come from, and that's where</p> <p>13 I'm trying to point you to. If you need me to, let</p> <p>14 me go into my documents real quick here, and on my</p> <p>15 computer, and I'll -- but I mean, they are cited.</p> <p>16 Let me look at my report -- actually, you know what?</p> <p>17 I think I cite to these in my report. Hold on, just</p> <p>18 a second.</p> <p>19 Q. Hold on a minute, we are short on time</p> <p>20 and unless you're citing to something that says that</p> <p>21 genotoxicity somehow cancels out 0.1 percent limit,</p> <p>22 that's not responsive to my question so I'd like to</p> <p>23 move on.</p> <p>24 A. Well, if you want me to answer the</p> <p>25 question, I need to look at my report because I do</p>

<p style="text-align: right;">Page 166</p> <p>1 have something that I believe is on point or at least 2 relevant to the question you're asking. So if you 3 don't want me to look, I won't. But I do believe 4 that I address this general issue in my report. Want 5 me to look -- 6 Q. You address -- do you address it with a 7 citation? 8 A. I believe I point to either the guidance 9 documents or to the general chapter, yes. Do you 10 want me to look? 11 Q. Yes, please. 12 (A pause in the proceedings.) 13 A. Okay, so this part of the relevant 14 information that I would point you to is not an 15 actual USP document, but it is the information that 16 is in the Drug Master File from ZHP. And this would 17 be paragraph 54 and I'm -- let me look further. 18 (A pause in the proceedings.) 19 A. Well, I'd also refer you to paragraphs 20 37 through 49 where the company is talking -- 21 "company" being ZHP -- was talking about their 22 recognition of not being compliant with GMP with the 23 presence of nitrosamines and then in addition to 24 that, there's information in -- further on pages 25 33-34, they talk about this issue of the fact that</p>	<p style="text-align: right;">Page 168</p> <p>1 to that. 2 Q. But that was the question I asked you 3 when you went to look at your report. 4 MR. VAUGHN: Objection, argumentative. 5 A. I understand, and I was looking to see 6 if I had pulled that language out and I had not 7 pulled it out specifically as a quote. But I do know 8 that the general chapters address that issue you're 9 raising. 10 Q. Let's go back to Exhibit 3 for a moment. 11 A. Exhibit 3, which one is that? 12 Q. It will pop up on the screen. 13 A. Oh, well, I might want to look at it, 14 that's -- 15 Q. It's the August 30, 2018 statement from 16 FDA. 17 MR. VAUGHN: In that share file 18 Dr. Plunkett, it's listed as Exhibit 3 for you also. 19 A. I was wondering whether it was an FDA 20 document or it was that article, that's why I was 21 asking. 22 (A pause in the proceedings.) 23 MS. MILLER: Are we still on page 2? 24 Okay, I have the wrong page number in my outline. 25 Q. If you could turn to page 3 here, I</p>
<p style="text-align: right;">Page 167</p> <p>1 nitrosamines are not to be present in these products, 2 so that's recognition that the monograph is not 3 covering nitrosamines. But if you're asking me for 4 the exact language you're asking me, I don't know, 5 I'd have to go look to see whether the USP had the 6 exact statement that you're asking. 7 But there are several elements in this 8 case to show that at issue here is the presence of 9 NDMA and NDEA at levels that may be below .1 percent, 10 but they are still a -- an issue with respect to the 11 product being pharmaceutically equivalent to the 12 Reference Listed Product. Different purity. 13 Q. You did not just point me to any USP 14 cite that says 0.1 percent clearly does not apply to 15 impurities that are potentially genotoxic, correct? 16 MR. VAUGHN: Objection, argumentative. 17 A. I told you, for that I would go to the 18 general chapters of the USP where they talk about 19 impurities. I don't have it cited, language out of 20 my report, but those are part of my -- 21 Q. The question I asked -- 22 A. -- if you would like me to pull them 23 out, we could look to that. 24 Q. That was -- 25 A. But I believe there is something similar</p>	<p style="text-align: right;">Page 169</p> <p>1 wanted to point you to this sentence that says, "We 2 estimated that if eight thousand people took the 3 highest Valsartan does, 320 milligrams, from 4 NDMA-affected medicines daily for four years, the 5 amount of time we believe the affected products had 6 been on the U.S. market, there may be one additional 7 case of cancer over the lifetimes of these eight 8 thousand people beyond the average cancer rate among 9 Americans." 10 Do you see that? 11 A. I do. 12 Q. Do you disagree with that statement? 13 A. I don't agree -- I haven't formed an 14 opinion one way or the other to agree or disagree. 15 This is what you and I spent a lot of time talking 16 about earlier today, where I said that there's an 17 issue -- there's two different issues to consider; 18 there is the issue of an increased risk and there's 19 the issue of whether or not you attempt to calculate, 20 and I have not done that, for individuals what that 21 increase risk will be. 22 There is risk, regardless of -- even 23 here, they are saying there is risk. There is an 24 additional cancer. So the question is then, how do 25 you handle that as a regulatory agency? They have</p>

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<p style="text-align: right;">Page 170</p> <p>1 duties, I mean, go to that if you want, but I 2 won't -- I won't draw that all back in, but I talked 3 a good bit about the issue of the context of what the 4 regulatory bodies would do versus what a toxicologist 5 would do when we talk about increased risk. 6 (A pause in the proceedings.) 7 Q. Let's move to Exhibit 4. If you look at 8 the third paragraph, it says, "Our analysis of NDMA 9 found that the risk to patients based on the maximum 10 possible exposure appears to be small." 11 Do you disagree with that statement? 12 A. I don't agree or disagree with it. I 13 haven't formed an opinion one way or the other. I 14 agree the statement is there, and what FDA has put 15 forward, but I'll -- it doesn't say that there is no 16 risk. 17 Q. Understood. Are you offering an opinion 18 as to whether or not the risk to patients from the 19 NDMA impurities in Valsartan was small? 20 MR. VAUGHN: Object to form. 21 A. I'm sorry, it's beyond the scope of what 22 I was asked to do. But is something I believe other 23 experts are handling in terms of quantifying the 24 risk. I believe there is a risk. I believe there's 25 an increased risk compared to when the product is</p>	<p style="text-align: right;">Page 172</p> <p>1 A. I have not quantified the risk. 2 Q. Okay. 3 A. As a result of that, as a result of 4 that, that's how I would make a judgement over small 5 or large. 6 However, I do believe that there is an 7 increased risk for any individual who would have 8 taken these drugs with NDMA and NDEA, based on the 9 fact that there is no level identified without risk. 10 Q. And that opinion applies even if the 11 person only took one pill, correct? 12 MR. VAUGHN: Objection. 13 A. It could apply, yes. It depends on the 14 person and the situation. But certainly, the issue 15 is, I'm not doing case-specific individual exposure 16 assessment. I'm talking about this in the context of 17 whether or not these products generally posed a 18 hazard to the patients who were taking it, and 19 whether or not there was something that could have 20 been done about it. 21 And certainly we know that the product 22 could be made without these impurities. 23 Q. If we could turn to page 19 of your 24 report, Exhibit 1? 25 A. Were you in paragraph 30?</p>
<p style="text-align: right;">Page 171</p> <p>1 made without it, and that's what's really important. 2 The point is, it's not supposed to be there. FDA 3 says that it's unacceptable, you need to take it out, 4 you need to make it -- you can make it, we know it 5 can be made without it, and that's what the 6 important -- the important finding is. 7 FDA only has to deal with these things 8 on, with an ongoing kind of a crisis in terms of drug 9 shortages and different things and so it's adapting 10 and learning and it's making statements over time. 11 Q. All right. I appreciate that speech, 12 but really I just want to know whether you think the 13 risk is small or -- 14 MR. VAUGHN: Oh, don't be argumentative 15 with her. And -- you made the comment you made. 16 MS. MILLER: Brett, do not interrupt -- 17 MR. VAUGHN: Jessica -- 18 MS. MILLER: -- no, Brett, you cannot 19 interrupt my questions, that's rude. 20 MR. VAUGHN: Okay, don't interrupt her 21 either. 22 MS. MILLER: I didn't interrupt her. 23 Q. Dr. Plunkett, you have no opinion on 24 whether or not this risk is small? 25 MR. VAUGHN: Object to form.</p>	<p style="text-align: right;">Page 173</p> <p>1 Q. I am. Do you see the language in bold 2 italics? 3 A. Yes, that I highlight, which is the 4 quote, yes? 5 Q. Can you read that sentence? 6 A. "However, identification should be 7 attempted for those potential impurities that are 8 expected to be unusually potent, producing toxic or 9 pharmacologic effect at a level lower than .1 10 percent." 11 Q. Do you know whether NDMA or NDEA 12 produces toxic or pharmacological effects at a level 13 lower than 0.1 percent? 14 A. Yes, based on the cancer risk assessment 15 that you would do, where there is no safe level of 16 exposure. So the issue would be, NDMA and NDEA would 17 be identified as carcinogens, as carcinogens and 18 genotoxins. They are compound where you can't 19 identify a no-risk level. 20 Q. And is -- are you saying that "can't 21 identify a no-risk level" is the same thing as 22 "expected to produce toxic or pharmacologic effects 23 at a level lower than 0.1 percent"? 24 A. Yes, when you're talking about a 25 carcinogenic agent. Because carcinogenic agents, you</p>

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<p style="text-align: right;">Page 174</p> <p>1 couldn't tend to regulate based like you do 2 non-cancer agents. Carcinogenic agents generally, 3 when, as FDA has said, they shouldn't be there, it's 4 unacceptable, it needs to come out, and that's the 5 issue. 6 Q. Have you done the work necessary to 7 determine whether NDMA or NDEA can produce toxic or 8 pharmacological effects at a level lower than 0.1 9 percent? 10 MR. VAUGHN: Object to form. 11 A. Are you -- I don't quite understand what 12 your asking. Are you asking me -- let me ask a 13 question. Are you asking me, did I do a quantitative 14 risk assessment? I've already told you I did not. 15 Others in -- other experts in the litigation are 16 doing that. 17 But regardless of whether it's at a 18 level lower than .1 percent, agents that are 19 genotoxicants, or carcinogens, are considered to pose 20 a hazard, increase the risk, have the ability to, in 21 some individuals, produce a toxic effect at a level 22 lower than that because you can't extrapolate to a 23 level that is "without risk." 24 Q. Can you point me to a single piece of 25 literature that states that NDMA or NDEA can produce</p>	<p style="text-align: right;">Page 176</p> <p>1 A. If you defined .1 percent in parts per 2 million, I'm sure you do. But I can't point to it, 3 because I -- I'm telling you, if you want me to do 4 that, it's beyond the scope of what I did, trying to 5 do a dose/response, quantitative risk assessment for 6 things other than cancer, or even a specific dose or 7 specific exposure pattern that would lead to an 8 increased risk of one in a hundred thousand versus 9 one in ten thousand versus one in a million. I have 10 not done that. Others in the litigation are doing 11 it, and they would be able to provide you that answer 12 to that question. 13 But I'm telling you, I'm sure you can 14 find this information in -- in some of the recent 15 sources that I have cited, but it was beyond the 16 scope of what I did. 17 Q. Do you know whether DMF reached a 18 boiling point during the manufacture of Valsartan? 19 MR. VAUGHN: Objection, foundation. 20 A. That was beyond any scope. I don't 21 recall, but that may be able to be found in the 22 chemist's report. I just don't recall. 23 Q. Do you know whether DMF has ever been 24 described to decompose in the circumstances in which 25 it decomposed in Valsartan?</p>
<p style="text-align: right;">Page 175</p> <p>1 toxic or pharmacological effects at a level lower 2 than 0.1 percent? 3 MR. VAUGHN: Objection, vague as to what 4 0.1 percent is referencing. 5 MS. MILLER: It's in this quote. 6 A. I would read this as .1 percent, which 7 would be a thousand parts per million. So can I find 8 a study? Possibly. Have I looked for it? No, 9 because when you talk about carcinogens, you don't 10 try to identify a threshold. That's what I'm trying 11 to tell you. 12 Now, if you're going to talk about, is 13 there a toxic effect that might occur at a level, 14 only a level higher? It's possible. But the issue 15 is, the overriding concern in terms of the safety of 16 exposure to NDMA and NDEA, is the carcinogenic and 17 genotoxic potential, not other types of toxicity 18 which might occur at higher levels. I point you to 19 the discussion of this in the NTP, ROC document that 20 I cite to, and also all of the studies that are gone 21 through as part of the IARC evaluation as well. 22 Q. But you don't know whether any of those 23 studies actually found a toxic or pharmacological 24 effect at a level lower than 0.1 percent? 25 MR. VAUGHN: Objection vague.</p>	<p style="text-align: right;">Page 177</p> <p>1 MR. VAUGHN: Objection, vague, 2 foundation. 3 MS. MILLER: I can ask the question 4 differently if you don't understand it. 5 A. Well, I'm not the chemist so the 6 question you're asking I think is beyond the scope of 7 the opinions that I have formed. But I would -- I 8 would -- maybe we should be careful to make sure that 9 when you're saying DMF, you mean the chemical, not 10 the drug master file. For the purposes of the court 11 reporter, there's that abbreviation is used two 12 different ways. 13 Q. I don't think any Drug Master File is 14 decomposed here, so I think we are all understanding 15 what we're talking about. 16 You say it's beyond the scope of your 17 opinions, but you do offer the opinion that it has 18 been known, right? 19 MR. VAUGHN: Objection, norm. 20 Q. If you offer the opinion that it has 21 been known that DMF can decompose in certain 22 circumstances, right, is that one of your opinions? 23 A. It's -- it's my -- it's my opinion that 24 it was known before this product was -- you had this 25 issue with this product, but if they had done a</p>

<p style="text-align: right;">Page 178</p> <p>1 chemical risk assessment, they would have been able 2 to understand the potential for formation of 3 genotoxic impurities like the nitrosamines. I, 4 however, did not attempt to do an analysis or root 5 cause analysis or even a full chemical analysis of 6 their processes. 7 Again, that was what the chemist has 8 done in this case. That was beyond my scope. 9 Q. Since you do offer an opinion that it 10 was known that DMF could decompose in certain 11 circumstances, can you tell me what those 12 circumstances are? 13 A. That was beyond the scope of what I did. 14 I'm pointing to the literature. I think you're 15 taking that from the literature when I talk about the 16 literature section, I believe. And those papers 17 would speak for themselves, I believe. And I'm 18 citing to them on the issue of, there was evidence to 19 show that before 2012, there was chemical information 20 that the company, ZHP, could have identified if they 21 had done a literature search and attempted to look, 22 if they didn't understand that process, could have 23 gone to the literature to figure out if there was 24 something about their intermediates or -- or process 25 ingredients that would pose a risk of genotoxic</p>	<p style="text-align: right;">Page 180</p> <p>1 afternoon? 2 A. If you define "did not pursue" in terms 3 of "did not resolve," that is true. I had no 4 evidence in this case to show that they attempted to 5 identify what those impurities were. 6 Q. Let's turn to -- 7 MS. MILLER: -- Alex, what exhibit are 8 we up to? I think six or seven. 9 Q. Okay, let's go to tab 43 and mark it as 10 Exhibit 6. 11 EXH (Plunkett Exhibit 6, e-mail chain Bates 12 numbered ZHP00492652 through 92659, marked for 13 identification, as of this date.) 14 Q. Dr. Plunkett, this is an e-mail train 15 from September 2017. Have you seen it before? 16 MR. VAUGHN: Would you let me know what 17 this is -- 18 MS. MILLER: I'm just asking if she's 19 seen it before, then I'll let her read it, obviously. 20 (A pause in the proceedings.) 21 A. I need to see the -- further into the 22 e-mail, you know, because -- is it up where I can 23 take a look real quick, tell you if I've seen it? 24 MS. MILLER: Why don't we follow that 25 procedure of going off the record --</p>
<p style="text-align: right;">Page 179</p> <p>1 impurities. 2 Q. For that opinion you cite an Australian 3 textbook which you found in prior depositions in this 4 litigation, correct? 5 A. It was something that was cited and 6 testified to in deposition testimony in the 7 litigation, that is correct. 8 Q. Have you ever seen that Australian 9 textbook before this litigation? 10 A. You already asked me that and I said I 11 had not, I said I had not seen that textbook, it's 12 not one that I have in my library. 13 Q. You testified earlier today that ZHP did 14 not pursue complaints about potential peaks, is that 15 correct? 16 A. I don't think that's exactly what I 17 said. I think I said, I think what I said is 18 consistent with what's in my report, where I talked 19 about the fact that they had, were on notice or had 20 reports of impurities that they apparently did not 21 resolve, in other words, if you look at the 22 testimony. So am I going to find that in my report 23 for you? 24 Q. Where did you use that language, "Did 25 not pursue," is that still your opinion this</p>	<p style="text-align: right;">Page 181</p> <p>1 A. I don't necessarily need to read it 2 carefully. I just need to look at the whole document 3 to tell you whether I -- 4 Q. I'm going to ask you some questions 5 about it. I thought I could -- 6 MR. VAUGHN: Can you guys just put it 7 into the share file like the procedure is so she can 8 look to see if she's seen it -- 9 MS. MILLER: We did. We did, Brett. 10 MR. VAUGHN: I just asked if you guys 11 would tell me when you have. I'm refreshing it and I 12 don't -- okay. 13 THE WITNESS: I didn't see -- 14 MR. VAUGHN: It just went in. 15 MS. MILLER: Alex is doing it as quickly 16 as he can. 17 MR. VAUGHN: Sorry, Alex. 18 A. I need to be able to look at it so I 19 need you to stop share, I don't know how to get to it 20 otherwise. 21 Q. Okay. 22 MS. MILLER: We're going to go off the 23 record because it's eight pages for you to read it, 24 and then just let me know when you're done. 25 VIDEOGRAPHER: Going off the record.</p>

<p style="text-align: right;">Page 182</p> <p>1 The time is 3:13 p.m. 2 (Discussion off the record.) 3 (A pause in the proceedings.) 4 VIDEOGRAPHER: We're back on the record. 5 The time is 3:17 p.m. 6 Q. Dr. Plunkett, now that you've read this 7 e-mail chain, have you seen it before? 8 A. I didn't recall this one, but within a 9 time period where I had seen some, and I went back 10 and compared it with my reliance material list, 11 unless it has a different Bates number than you have 12 on the bottom, I don't know if I've seen this. 13 Now if it was an exhibit to a depo I've 14 read, then I just may not remember it. 15 Q. This is an e-mail exchange between ZHP 16 and Aurobindo, correct? 17 A. Yes. That's correct -- well, yes, 18 that's correct. 19 Q. Is it correct that Aurobindo is raising 20 questions about unknown peaks? 21 A. Can you just show me where it is you're 22 referring to? I assume it's in the later pages of 23 the document. 24 (A pause in the proceedings.) 25 Q. If you look at page 2656, paragraph 2.</p>	<p style="text-align: right;">Page 184</p> <p>1 MR. VAUGHN: Objection, that is not what 2 it says, it says "identified some unknown peaks." 3 A. So they didn't identify everything. And 4 in fact, they mention -- I was going to say they 5 mention that the peak at 13 they say they didn't see, 6 but I -- I don't disagree with you, this is an e-mail 7 discussing some questions from Aurobindo. 8 Q. Does this e-mail suggest that ZHP did 9 pursue unknown peaks? 10 MR. VAUGHN: Objection, form. 11 A. Well, there is other testimony that 12 indicates they did not always pursue unknown peak 13 questions from their -- their customers, or the 14 people they were supplying to. 15 Q. In this instance, did ZHP pursue these 16 unknown peaks? 17 MR. VAUGHN: Object to form. 18 A. I can't tell you the complete level of 19 what their pursuit was, but I don't disagree with you 20 that they are describing some results for some peaks 21 in a question that was raised by Aurobindo in that 22 case, that is correct. 23 Q. I mean, if you look to the next page, 24 2653, because with e-mail chains, you go up, not 25 down, they say, "Regarding R214.5, we need little</p>
<p style="text-align: right;">Page 183</p> <p>1 A. And as it relates to the residual 2 solvents they are asking some questions, yes. 3 Q. Based on this e-mail chain, does it 4 appear that ZHP pursued these unknown peaks to 5 determine what they are? 6 A. I -- I don't recall whether -- the 7 testimony around this to know whether that is true 8 for all the peaks, but certainly, there is a 9 discussion in this part of the e-mail that they were 10 answering some questions, that is true. 11 Q. In fact, if you look at page 2654, each 12 of the peaks is listed, right? And then it says, 13 "HH." Right? 14 A. Again, I don't recall this document so 15 if you want me to confirm that it is a complete 16 discussion or -- I would need to see accompanying 17 information with it. I don't recall this document, 18 so -- 19 Q. I understand. But I'm asking you 20 reading it now, do you see the "HH:"? 21 A. I don't see "HH." Where are you 22 referring to? Okay. 23 Q. So ZHP is saying here, "We did a study 24 and we identified unknown peaks and here is the 25 explanations," is that correct?</p>	<p style="text-align: right;">Page 185</p> <p>1 more time to do further tests." Correct? 2 A. You have read that correctly, yes. By 3 "MS," yes, that's the -- 4 Q. And it suggests that ZHP was doing 5 testing to understand these unknown peaks, correct? 6 MR. VAUGHN: Objection, form, 7 foundation. 8 A. Again, not having seen the context 9 around this, I can only tell you what the e-mail says 10 and I would agree with you this particular e-mail is 11 showing that at this particular point in time from 12 Aurobindo, they were investigating some unknown 13 peaks. 14 Q. In preparing -- 15 A. And use the residual solvent methods. 16 Q. -- in preparing your report, did you ask 17 to see all occasions in which ZHP followed up to 18 pursue claims of unknown peaks? 19 MR. VAUGHN: Object to form. 20 A. I don't think I did, no. 21 Q. Why not? 22 A. I thought that was beyond the scope of 23 what I was doing in terms of an analysis -- I wasn't 24 doing a GMP compliance analysis, in the way other 25 experts were doing. So it was my understanding that</p>

<p style="text-align: right;">Page 186</p> <p>1 other experts were following up on many of these 2 interactions with other companies. 3 Q. But you're offering an opinion that ZHP 4 did in the pursue claims of unknown peaks, correct? 5 A. There certainly is evidence that they 6 did not always pursue, that is correct, based on 7 other documents that I have seen. 8 Q. Is this document relevant to your 9 opinions? 10 A. Well, it would provide an evidence that 11 in this particular case, for this particular 12 question, they were following up, but they weren't 13 following up based upon some of the other information 14 that I have seen. 15 Q. And what is that other information? 16 (A pause in the proceedings.) 17 A. So it's the deposition testimony of 18 Dr. Li that I discuss in paragraph 48. 19 Q. Paragraph? 20 A. Forty-eight. In my report. 21 Q. Okay. 22 A. So I'd have to pull this out. 23 Q. Okay. 24 A. What I'm citing to you what I would be 25 relying upon for that opinion, or that statement</p>	<p style="text-align: right;">Page 188</p> <p>1 why don't we go off the record for you to read it 2 because I will have some questions about it. 3 VIDEOGRAPHER: All right, going off the 4 record. The time is 3:26 p.m. 5 (Recess taken.) 6 VIDEOGRAPHER: Stand by, just a few 7 moments. We are back on the record. The time is 8 3:31 p.m. 9 EXAMINATION (Cont'd.) 10 BY MS. MILLER: 11 Q. Dr. Plunkett, having had some time to 12 take a look at this, do you recall whether you read 13 it before? 14 A. It is on my reliance list. I don't 15 recall reading it. And a lot of what's covered in 16 here, a lot of it would have been something that I 17 felt would be beyond the scope of what I was doing 18 but were more relevant to the GMP expert and the 19 potentially the chemists, because it deals with the 20 issue of validation. But it does talk about unknown 21 peaks in the very top e-mail. It indicates that the 22 customer is asking some questions about things that 23 haven't been resolved yet. 24 Q. What's going on? 25 A. The customer, based on what I'm saying</p>
<p style="text-align: right;">Page 187</p> <p>1 actually. 2 Q. So that statement just relies on 3 Dr. Li's testimony, correct? 4 A. Well, the documents that accompany it, 5 too, yes. 6 Q. Are there documents accompanying those 7 pages of testimony? It's only one page, right? 8 A. 261 to 265, page 268, it's the 9 discussion that's going on through here. So I'd have 10 to go pull it back out, but... 11 Q. Okay. And let's turn to tab 46, which 12 would be Exhibit 7. Okay, we're going to mark 13 Exhibit 7. 14 MS. MILLER: Don't worry, Brett, you're 15 going to get it. 16 MS. VAUGHN: Thank you, Jessica. 17 MS. MILLER: Forty-six. 18 EXH (Plunkett Exhibit 7, e-mail chain Bates 19 numbered ZHP02118712 through 8731, marked for 20 identification, as of this date.) 21 Q. Dr. Plunkett, do you know if you've seen 22 this e-mail chain before? 23 A. I'd need to compare it with the Bates 24 number, can you put that up for me? 25 Q. Okay. So this is another long one, so</p>	<p style="text-align: right;">Page 189</p> <p>1 about again, this is not a document I cited to in my 2 report, so I'd have is to go back and look at the 3 deposition testimony around this as well. 4 Q. In this document, is Glenmark asking ZHP 5 to identify certain unknown peaks? 6 A. It's -- Glenmark is -- in the top 7 e-mail, it's a series of e-mails about impurities and 8 peaks and then at the top e-mail, Francis Dsouza from 9 Glenmark is asking whether or not -- these are some 10 things that haven't been resolved, so they are sore 11 points. 12 Q. Um-hum. And if you look -- 13 A. That's all I can tell you because I 14 don't recall this document's discussion in any of 15 the -- in the depositions, I'd have to go back and 16 look. 17 Q. If you look to page ZHP02118713, which 18 is the second page of the document, it's an e-mail 19 from ZHP in which he says, "Dear Francis, we 20 investigating the same on our side," correct? 21 A. Yes, you've read that correctly. But 22 this is, you -- that's all I can tell you. Because I 23 haven't -- I'd have to go look at the deposition 24 testimony for the context for this one. 25 Q. Based on this document, does it appear</p>

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<p style="text-align: right;">Page 190</p> <p>1 that ZHP was following up on this issue?</p> <p>2 A. Well, they hadn't totally followed up by</p> <p>3 the last e-mail in the chain, but they certainly were</p> <p>4 doing some work, that is true.</p> <p>5 Q. And what's the date of this e-mail</p> <p>6 chain?</p> <p>7 A. I think it's 2016, December. I don't</p> <p>8 know when the first one starts, whether it was in</p> <p>9 November, but it certainly is December.</p> <p>10 Q. All right. And now let's look at tab</p> <p>11 48, which we're going to mark as Exhibit 8.</p> <p>12 EXH (Plunkett Exhibit 8, e-mail chain Bates</p> <p>13 numbered ZHP02118681 through 8711, marked for</p> <p>14 identification, as of this date.)</p> <p>15 Q. And this is dated April 2017, correct?</p> <p>16 A. I don't know, I don't have it yet.</p> <p>17 Q. Tab 48 is an e-mail chain, and the top</p> <p>18 e-mail is dated April 20137, correct?</p> <p>19 A. I'm waiting for you to upload it so you</p> <p>20 can look at it.</p> <p>21 Q. Can you see on the computer screen that</p> <p>22 it's dated April 2017?</p> <p>23 A. Yes, April 20th, the first page I see</p> <p>24 that.</p> <p>25 Q. And the -- and at the top of the page,</p>	<p style="text-align: right;">Page 192</p> <p>1 on-and-off.</p> <p>2 VIDEOGRAPHER: Going off the record.</p> <p>3 The time is 3:35 p.m.</p> <p>4 (Recess taken.)</p> <p>5 VIDEOGRAPHER: We are back on the</p> <p>6 record. The time is 3:39 p.m.</p> <p>7 EXAMINATION (Cont'd.)</p> <p>8 BY MS. MILLER:</p> <p>9 Q. Just is to reorient us, we're looking at</p> <p>10 Exhibit 8. Exhibit 8 is an e-mail chain between</p> <p>11 Glenmark and Huahai. Are you familiar with what</p> <p>12 Glenmark is, Dr. Plunkett, is that company familiar?</p> <p>13 A. You asked me that, and it looks like</p> <p>14 they are a pharmaceutical company. But I don't know</p> <p>15 what their relationship is with ZHP other than they</p> <p>16 are asking questions about materials used, they are</p> <p>17 actually talking about raw materials used in the</p> <p>18 manufacture of Valsartan.</p> <p>19 Q. But this is a follow-up on the e-mail</p> <p>20 chain we looked at earlier regarding unknown peaks,</p> <p>21 correct?</p> <p>22 A. Yes, but this one actually gives more</p> <p>23 context which is a little helpful. So, you know, the</p> <p>24 first ten pages or whatever were the same, if you go</p> <p>25 to the very first page of this exhibit, and the</p>
<p style="text-align: right;">Page 191</p> <p>1 in terms of the "re" line, it says, "Valsartan from</p> <p>2 Huahai -- Impurities and Unknown Peaks," correct?</p> <p>3 A. That's the title, yes.</p> <p>4 Q. And it's the same title as the last</p> <p>5 e-mail chain we were looking at, correct?</p> <p>6 A. I don't remember, but I think it --</p> <p>7 well, it looks like it's involving Glenmark, so my</p> <p>8 guess is it's somewhat related. I don't know for</p> <p>9 sure, I'd have to compare them.</p> <p>10 Q. And do you recall whether you reviewed</p> <p>11 this e-mail chain and its attachment in preparing</p> <p>12 your report?</p> <p>13 A. I don't recall it, but I can look and</p> <p>14 see where it's listed, so if you want me to look in</p> <p>15 my appendix C.</p> <p>16 Q. I did not find it there, for what it's</p> <p>17 worth.</p> <p>18 A. So if it's not in appendix C, then it's</p> <p>19 not what that I recall, no.</p> <p>20 Q. Would you like to read it before you</p> <p>21 answer questions about it?</p> <p>22 A. Surely, absolutely, because I don't --</p> <p>23 the question -- this one is 29 pages long.</p> <p>24 MS. MILLER: Lets go off the record</p> <p>25 again. I'm so sorry, court reporter, for all the</p>	<p style="text-align: right;">Page 193</p> <p>1 second page of the exhibit, and down to page 685, you</p> <p>2 get, the last three numbers, you get a little bit of</p> <p>3 context of what was going on.</p> <p>4 Q. There is an attachment to this document,</p> <p>5 in which ZHP has set forth the identification of each</p> <p>6 impurity, correct?</p> <p>7 MR. VAUGHN: Objection, form.</p> <p>8 A. I don't know what you're talking about.</p> <p>9 They indicated that there were certain things they</p> <p>10 have not resolved. This is raw material issues</p> <p>11 carryover.</p> <p>12 Q. If you look at the last three pages of</p> <p>13 the document, there is an attachment to the document</p> <p>14 that's a table and for each impurity, there is a</p> <p>15 column that says, "Origin of impurity," correct?</p> <p>16 A. I can't see it on the screen. If you</p> <p>17 would go to the last three pages, I can maybe answer</p> <p>18 your questions.</p> <p>19 MS. MILLER: 709.</p> <p>20 (A pause in the proceedings.)</p> <p>21 Q. Well, you can't look at it in your</p> <p>22 shared file?</p> <p>23 A. If you stop sharing screen so I can have</p> <p>24 access to my screen.</p> <p>25 Q. One second.</p>

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<p style="text-align: right;">Page 194</p> <p>1 A. So you want me to look at my screen?</p> <p>2 Q. Hold on, Alex is dealing with the</p> <p>3 technological problem.</p> <p>4 (A pause in the proceedings.)</p> <p>5 MS. MILLER: Alex is having a technical</p> <p>6 difficulty, we're going to go off the record for two</p> <p>7 minutes.</p> <p>8 MR. VAUGHN: It's just two minutes,</p> <p>9 let's just -- are we really --</p> <p>10 MS. MILLER: What if it turns into four</p> <p>11 and my time is waiting, so yes, please.</p> <p>12 VIDEOGRAPHER: Mr. Vaughn, you're</p> <p>13 agreeing?</p> <p>14 MR. VAUGHN: That's fine.</p> <p>15 VIDEOGRAPHER: Okay, going off the</p> <p>16 record, the time is 3:42 p.m.</p> <p>17 (Recess taken.)</p> <p>18 VIDEOGRAPHER: We're back on the record.</p> <p>19 The time is 3:57 p.m. Eastern Time. This is the</p> <p>20 beginning of media unit 5.</p> <p>21 EXAMINATION (Cont'd.)</p> <p>22 BY MS. MILLER:</p> <p>23 Q. Great. Dr. Plunkett, sorry about the</p> <p>24 technical difficulties, that seems to be the theme of</p> <p>25 the day. We have now fixed Exhibit 8, so we are</p>	<p style="text-align: right;">Page 196</p> <p>1 in other words, I would need to confirm that there</p> <p>2 were only twelve peaks being raised but I agree with</p> <p>3 you that there is a table that is talking about</p> <p>4 twelve peaks.</p> <p>5 Q. So you would agree that in this</p> <p>6 instance, ZHP pursued the origin of twelve peaks</p> <p>7 identified by a customer, is that fair to say?</p> <p>8 MR. VAUGHN: Object to form.</p> <p>9 A. Go back up, please, to the next page.</p> <p>10 Next page, please. I'm trying to read what the</p> <p>11 origin says.</p> <p>12 Q. Um-hum.</p> <p>13 A. So state your question again, please,</p> <p>14 I'm sorry, I don't mean to be rude, please.</p> <p>15 Q. Based on this e-mail chain, did ZHP</p> <p>16 follow up in an attempt to determine the origins of</p> <p>17 the impurities identified by Glenmark?</p> <p>18 A. In reading the entire, not just this --</p> <p>19 reading the entire e-mail, which isn't just this</p> <p>20 table, it's clear that there were questions being</p> <p>21 raised by Glenmark about -- about the Valsartan</p> <p>22 product materials. They did do some investigation.</p> <p>23 It's not clear to me, however, that they answered all</p> <p>24 questions at all times. But certainly, in here, they</p> <p>25 are answering some questions.</p>
<p style="text-align: right;">Page 195</p> <p>1 reintroducing Exhibit 8 which is an e-mail chain that</p> <p>2 says at the top, "Re, re, Valsartan from Huahai,</p> <p>3 Impurities and Unknown Peaks."</p> <p>4 The last-in-time e-mail, which is on the</p> <p>5 first page, is April 20, 2017, and there is an</p> <p>6 attachment to the e-mail which is the last two pages</p> <p>7 right here. Those highlights are not -- we did not</p> <p>8 make those highlights, that's how we received the</p> <p>9 document. Just to be clear.</p> <p>10 And before we went off the record, I was</p> <p>11 asking you whether the attachment to the document</p> <p>12 includes an explanation for each of the impurities</p> <p>13 identified by Glenmark.</p> <p>14 A. Did I see the second -- if there's two</p> <p>15 pages, may I see the second page?</p> <p>16 Q. Of course.</p> <p>17 (A pause in the proceedings.)</p> <p>18 A. I can't confirm about looking back at</p> <p>19 the rest of the e-mail whether there were only ten</p> <p>20 peaks in question, but I would agree that for at</p> <p>21 least ten of these, they are giving information.</p> <p>22 Q. And there's a third page, I apologize.</p> <p>23 A. So, okay.</p> <p>24 Q. And that goes to twelve peaks.</p> <p>25 A. So same answer, that I would say twelve;</p>	<p style="text-align: right;">Page 197</p> <p>1 However, this entire thing that we see</p> <p>2 here, if you go to page ending in 685 on this e-mail</p> <p>3 string, it's interesting that ZHP is admitting that</p> <p>4 they didn't always follow the same types of</p> <p>5 procedures because FDA wasn't so picky. I thought</p> <p>6 that was practically interesting. In other words,</p> <p>7 it's clear that not necessarily over the years has</p> <p>8 ZHP always done the same thing.</p> <p>9 Q. Now, in your expert report, I believe</p> <p>10 you said you cite the Li deposition on pages 261 to</p> <p>11 267 for your opinion that ZHP did not follow up on</p> <p>12 unknown peaks, correct?</p> <p>13 A. I say that ZHP had received complaints</p> <p>14 from customers beginning in 2014 of unknown peaks</p> <p>15 identified through chromatography that ZHP failed to</p> <p>16 investigate, yes, that's what it says.</p> <p>17 Q. And your basis for "ZHP failed to</p> <p>18 investigate" is the testimony of Li?</p> <p>19 A. Yes, there was a company, a corporate</p> <p>20 witness brought in to answer questions about their</p> <p>21 procedures and process.</p> <p>22 Q. Okay.</p> <p>23 MS. MILLER: So let's introduce as</p> <p>24 Exhibit 9, Min Li's deposition.</p> <p>25 EXH (Plunkett Exhibit 9, transcript of</p>

<p style="text-align: right;">Page 198</p> <p>1 deposition of Min Li, Ph.D., marked for 2 identification, as of this date.) 3 Q. Do you have a hard copy of that with you 4 today or not? 5 A. No, I didn't, it's too much to print 6 out, so saving some trees. 7 Q. I think you said you were looking at 8 pages 261 to 267, correct? 9 A. Lets see. 10 MR. VAUGHN: Objection, misstates the 11 record -- 12 A. When I read to 261 to 265, and then 268 13 as well. 14 Q. Okay, great. Can you show me where Min 15 Li says, "We didn't follow up on complaints about 16 unknown peaks"? 17 A. So it would -- could you -- well, I'm 18 going to need to scroll through, so do you want to 19 put this up so I can really quickly look? It won't 20 take but a minute, or is this an exhibit that you're 21 marking or not? 22 Q. We already marked it. 23 A. So let me go, if you let me out, it 24 would take but a minute. I don't think I need to 25 stop the clock.</p>	<p style="text-align: right;">Page 200</p> <p>1 Q. That's not my question. 2 A. No, but I need to go further, okay? So 3 that's the first part of the statement. All right. 4 So now I need to -- let me go back and look for the 5 second part. I'll need to be able to get back to the 6 document again, please. Thank you. 7 (A pause in the proceedings.) 8 A. Unfortunately, you have to read through 9 all of these pages, he's answering questions about -- 10 and he qualifies them at different times where some 11 of those questions were treated like technicals, some 12 of them, they couldn't figure out, they didn't know 13 what they were, they didn't identify them. 14 So this is the basis, the testimony that 15 I'm pointing to is throughout this entire exchange 16 and unfortunately, because it is English as a second 17 language, sometimes it's a little stilted to read. 18 Q. If we could turn to page 266, lines 16 19 through 20, can you read that to me? 20 A. I think -- you're starting with "I 21 think"? 22 Q. Um-hum. 23 A. "I think, you know, in the end, you 24 know, we -- for all the concerned peaks, you know, I 25 think, you know, we were able to find the identity or</p>
<p style="text-align: right;">Page 199</p> <p>1 Q. If it's just a minute, that's fine. I 2 only try to stop the clock when it's more than five 3 to ten. 4 (A pause in the proceedings.) 5 A. So starting on page 261, you have 6 that -- you had it up at line 17, where he's, that's 7 where the initial question comes. So then you have 8 to scroll through. And he says, "Yeah, for some, you 9 now, during the later stage of the investigation, you 10 know, yeah," and he talks about Novartis, Sun Pharma 11 at the time, keep going -- 12 Q. I'm just asking where does he say that 13 they didn't pursue or follow up on the complaints? 14 A. I think that's the answer to the 15 question, it starts on page 261. 16 Q. What are the words, can you just show me 17 the words where he says, "We didn't follow up"? 18 A. He's asked that question, and he 19 responds, "Yes." So when the question is being 20 asked -- go to the question. "You're aware that 21 starting in 2014, complaints came in on a regular 22 basis asking for answers, you do know that there were 23 multiple complaints and requests for information." 24 So that's the acknowledged to, yes, he's aware that 25 were complaints in 2014.</p>	<p style="text-align: right;">Page 201</p> <p>1 the potential sources." 2 Q. Do you quote that in your report? 3 A. These four lines, no. But again, if you 4 read his deposition, and the -- and the questions 5 that were coming in, it's clear that he's talking 6 about -- about not having followed up on everything, 7 but he is saying that they did identify potential 8 sources, which would be, I'm not saying that they 9 didn't ever identify potential sources, I just know 10 that they didn't follow up and they never went 11 through the process to determine whether or not their 12 process was producing something that they should be 13 looking for. 14 Q. He says, "For all of the concerned peaks 15 we were able to find the identity." Correct? 16 A. Well, "Concerned peaks," yes, but that 17 doesn't mean every peak. 18 Q. All the ones that people expressed 19 concerns about, right? 20 A. Again, I don't know what to tell you but 21 when I read this section, to me this section as 22 telling me that they were acknowledging that they had 23 received complaints of unknown peaks; and it's my 24 opinion, based upon all the documents I reviewed, 25 that they indeed failed to investigate all of those.</p>

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<p style="text-align: right;">Page 202</p> <p>1 Q. Is there a single sentence here in which 2 Min Li says, "We did not follow up or pursue claims 3 of unknown peaks"?</p> <p>4 A. On these pages we're looking at, I don't 5 see that language. That is your quoting it.</p> <p>6 Q. But those are the pages that you cite 7 for the opinion that ZHP did not follow up on unknown 8 peaks, correct?</p> <p>9 A. Yes, that's correct.</p> <p>10 Q. And sitting here today, you can't 11 actually find that language, correct?</p> <p>12 A. The language as a quote, no. But again, 13 if you read his deposition, and look at his 14 discussion here of what they are or aren't doing, he 15 talks about not necessarily having it; but go back up 16 further, in the -- in the -- he says, "I don't 17 know" -- okay. Unknown peaks, he says, "That's a 18 correct statement," right? He says, "Okay, as I 19 indicated, no, it was not informed, you know 20 initially, and some of this conversation, you know, I 21 said I was being consulted or I was trying to help 22 them and find out the identity."</p> <p>23 Q. Does that say ZHP did not follow up?</p> <p>24 A. I'm saying to you that it's my opinion, 25 based on this testimony plus other documents in the</p>	<p style="text-align: right;">Page 204</p> <p>1 determine what that that peak was.</p> <p>2 Q. But that's not what we're talking about, 3 right? We're talking about that ZHP received 4 complaints from customers beginning in 2014 of 5 unknown peaks identified through chromatography, that 6 ZHP failed to investigate. And what you cite for 7 that is Dr. Li's deposition, correct?</p> <p>8 MR. VAUGHN: Object to the colloquy.</p> <p>9 A. I cite to his deposition and then if you 10 go on and read through the paragraph --</p> <p>11 Q. I'm just --</p> <p>12 MR. VAUGHN: Do not interrupt my expert.</p> <p>13 This is twice. Want to ask your question again?</p> <p>14 A. No, if she'll let me finish, I'll go 15 ahead. And what I was going to say is, further in 16 this -- this wasn't Dr. Li's written but further in 17 this paragraph, I am discussing the evidence in the 18 case which is discussed in Dr. Li's deposition, about 19 the NDMA with Valsartan, and the documents that in 20 that -- that surround that, and I'd have to pull this 21 Princeton document out.</p> <p>22 But there's other documents that have 23 the back-and-forth and it's clear that Novartis is 24 the one that was having to push the company and then 25 it gives up and goes and does the identity, and then</p>
<p style="text-align: right;">Page 203</p> <p>1 case that they did not follow up on all of the 2 unknown peaks, that's --</p> <p>3 Q. Well --</p> <p>4 A. For no other reason, you know, you have 5 the Novartis issue and Novartis raised questions 6 where Novartis had to do work to identify the peak. 7 Instead what the company did is, said, "It's not a 8 problem," and Novartis found the peak.</p> <p>9 Q. When you say "plus other documents in 10 the case," are there other documents in which ZHP has 11 testified, an ZHP witness has testified that ZHP did 12 not follow up on unknown peaks?</p> <p>13 A. Let me look.</p> <p>14 Q. I only cite --</p> <p>15 A. I know, but let me look at other -- at 16 some of the other things that I cite to.</p> <p>17 So the -- I'll point you to the second 18 half of paragraph 48 for sure, where that was what I 19 was just talking about, was the idea of the -- that's 20 the discussion of the NDMA from Novartis, that 21 Novartis identified, and if you read the documents 22 around that time period, when Novartis was asking 23 questions, it's clear that they were not getting a 24 response from -- ZHP was not responding, and -- and 25 Novartis was the one who was being forced to</p>	<p style="text-align: right;">Page 205</p> <p>1 lets the company know that it had identified NDMA, 2 and "the company" being ZHP. So Novartis was doing 3 an investigation, a full investigation to find the 4 peak and not giving up even if it had to do 5 additional types of testing to determine what it was.</p> <p>6 Q. When you say ZHP failed to investigate, 7 you cite on pages 261 to 265 of Dr. Li's deposition 8 in that sentence, correct?</p> <p>9 A. At the end of that sentence, that's what 10 I cite, that's right.</p> <p>11 Q. And you do not cite page 266, 12 where Dr. Li says, "I think you know in the end, you 13 know, for all the concerned peaks, you know, I think 14 you know we were able to find the identity of the 15 potential sources." You didn't cite that, right?</p> <p>16 MR. VAUGHN: This is getting quite 17 argumentative, especially with your tone.</p> <p>18 A. I did not cite specifically the last 19 page, that is correct. But again, if you read the 20 rest of my paragraph in this section of my report, I 21 am referring to the entirety of the evidence in this 22 case, which includes what went on with the questions 23 raised by Novartis, as well, which is also one of its 24 customers.</p> <p>25 Q. You testified earlier about a 2017</p>

<p style="text-align: right;">Page 206</p> <p>1 e-mail from Jinsheng Lin, correct?</p> <p>2 A. I said I have one discussed in my</p> <p>3 report, yes. Is that what you're referring to?</p> <p>4 Q. You testified about it earlier and you</p> <p>5 said there was a 2017 e-mail.</p> <p>6 A. Yes, that's in paragraph 47.</p> <p>7 Q. Do you know whether that e-mail is</p> <p>8 written in English or Chinese?</p> <p>9 A. There's an English translation that was</p> <p>10 provided as part of the deposition testimony which is</p> <p>11 where I -- it's -- that's the version of the document</p> <p>12 that I reviewed and relied upon. They had a Chinese</p> <p>13 version and then they had a translated version.</p> <p>14 Q. Are you aware that there are multiple</p> <p>15 translations of that document?</p> <p>16 A. I am aware of the version that was used</p> <p>17 as part of the deposition, which typically in my</p> <p>18 experience is a version that I can rely on as being</p> <p>19 an accurate reflection of what the e-mail says.</p> <p>20 Q. Did you read on the report of ZHP's</p> <p>21 chemist expert, Fengtian Xue?</p> <p>22 A. Is this the report of this individual?</p> <p>23 Q. Um-hum.</p> <p>24 A. Yes, I have read that.</p> <p>25 Q. You read Dr. Xue's fluent in Chinese?</p>	<p style="text-align: right;">Page 208</p> <p>1 of identifying the --</p> <p>2 A. I don't cite to it, I don't think. It</p> <p>3 may be in my reliance material. If you could tell me</p> <p>4 whether it is or not, or show it to me and I'll</p> <p>5 confirm if it's there or not.</p> <p>6 Q. I'm just asking --</p> <p>7 A. I already answered, I said I don't</p> <p>8 recall. It's possible it's one that I just don't</p> <p>9 recall.</p> <p>10 Q. Are you offering any opinions about</p> <p>11 ZHP's handling of the recall?</p> <p>12 A. No, that was beyond the scope of what I</p> <p>13 did. However -- however, I do have opinions in my</p> <p>14 report where I talk about the issues that led up to</p> <p>15 the recall, which is having to do with the fact that</p> <p>16 in is something that shouldn't have -- shouldn't have</p> <p>17 occurred if ZHP had done its work to start with.</p> <p>18 Q. Are you offering any opinions about any</p> <p>19 of ZHP's conduct from the time of the recall forward?</p> <p>20 A. I don't believe in my report I'm</p> <p>21 addressing that, no. Although I would say that the</p> <p>22 one thing I do address after that time period has to</p> <p>23 do with the 2019 letter from FDA where they actually</p> <p>24 are letting ZHP know that indeed, their product was</p> <p>25 adulterated.</p>
<p style="text-align: right;">Page 207</p> <p>1 A. I don't know him. I know he states that</p> <p>2 he is, that's correct.</p> <p>3 Q. Are you aware that he lived in China for</p> <p>4 the first 25 years of his life?</p> <p>5 A. I don't know. I don't recall what his</p> <p>6 CV showed, but my answer to this line of questioning</p> <p>7 would be, in the deposition, when the document is</p> <p>8 used with the employees of ZHP, nowhere does anyone</p> <p>9 correct the translation around that document, that's</p> <p>10 all I can say. I rely on the translations as part of</p> <p>11 the exhibits to depositions all the time.</p> <p>12 Q. How did Dr. Xue translate the e-mail?</p> <p>13 A. I don't recall, I'd have to pull his</p> <p>14 report back out. They certainly didn't retranslate</p> <p>15 all of these sections that I have looked at, I don't</p> <p>16 believe.</p> <p>17 Q. Do you recall an e-mail in which</p> <p>18 Novartis commented that ZHP support throughout the</p> <p>19 process of identifying NDMA had been exceptional?</p> <p>20 A. Would you show me what you're referring</p> <p>21 to? I don't recall that. If you'll show me the</p> <p>22 e-mail, I'll let you know if I've seen it.</p> <p>23 Q. Do you recall whether you cited in your</p> <p>24 report an e-mail in which Novartis stated to ZHP that</p> <p>25 its support had been exceptional during the process</p>	<p style="text-align: right;">Page 209</p> <p>1 Q. Are you offering any opinions of ZHP's</p> <p>2 responses or conduct in the face of the FDA's warning</p> <p>3 letter?</p> <p>4 MR. VAUGHN: Object to form.</p> <p>5 A. So that was beyond the scope, I believe,</p> <p>6 of what I did; so, no. I don't think you'll find</p> <p>7 that in my report.</p> <p>8 Q. Are you offering an opinion as to</p> <p>9 whether ZHP's corrective actions were adequate?</p> <p>10 MR. VAUGHN: Object to form.</p> <p>11 A. So be more specific what you mean by</p> <p>12 "corrective action."</p> <p>13 Q. The corrective action ZHP took in</p> <p>14 response to the 2018 warning letter.</p> <p>15 A. So to answer that fully, I'd have to</p> <p>16 pull out whatever letter it is that you're saying</p> <p>17 that they did.</p> <p>18 Q. I'm asking you if you're offering an</p> <p>19 opinion in this litigation about ZHP's corrective</p> <p>20 actions in response to the November 20189 warning</p> <p>21 letter.</p> <p>22 A. In order to answer that fully, I need to</p> <p>23 see the letter you're referring to in order to see</p> <p>24 whether or not anything in that letter is directly</p> <p>25 addressed by the opinions I have expressed, that's</p>

<p style="text-align: right;">Page 210</p> <p>1 all I'm saying to you. I don't recall citing to that 2 letter but some of things that I discuss may indeed 3 be relevant to what is in that letter. 4 Q. Well, I'm just asking if you have any 5 opinions in this litigation regarding the corrective 6 actions that ZHP took after November 2018 in response 7 to the FDA warning letter that we've discussed 8 earlier today? 9 MR. VAUGHN: Objection, asked and 10 answered. 11 A. Again, in order to answer that question 12 fully, I need to see the letter, which I don't 13 recall, and whether or not any of the opinions in the 14 paragraphs are expressed where I talk about the 15 responsibility of the company and those kinds of 16 things and what they were required to do, whether 17 there was any -- anything there that would answer 18 your question. And I can't do that without looking 19 at the letter. So if you put up an exhibit, I can 20 take a quick look. 21 Q. Did you just say you don't recall the 22 November 18 warning letter? 23 A. I don't recall what response. You asked 24 me about the corrective actions in response but I 25 don't recall that. I'd have to pull that up.</p>	<p style="text-align: right;">Page 212</p> <p>1 product. 2 Q. Which types of CGMP violations do you 3 believe lead to adulteration? 4 A. Things that have to do with the purity, 5 identity, strength of the the product, violations 6 that lead to -- when I say "identity," they are 7 adulterated products that may end up having something 8 in them that isn't supposed to be there, not an 9 impurity, but an active ingredient that carry a -- 10 another active ingredient along, like having Fentanyl 11 in a morphine tablet would be an adulterated product 12 because of the issue of the potency and the danger 13 that's posed there. 14 Certain kinds of GMP violations, 15 however, such as recordkeeping violations, or minor 16 ones, may not lead to a warning letter and a finding 17 of adulteration. It may -- instead, they may be 18 written up in a 483, without a warning letter. So a 19 483 would be issued, and it may or may not be 20 accompanied by a warning letter that would deem the 21 products adulterated because of GMPs. 22 Q. Is it your opinion that any time a 23 generic drug has an impurity that the manufacturer 24 did not identify through its risk assessment, that 25 there was a CGMP violation?</p>
<p style="text-align: right;">Page 211</p> <p>1 Q. If a company engages in CGMP violations, 2 does that mean that its products are adulterated? 3 A. The definition that is provided within 4 the regulations, CGMP violations lead to adulterated 5 products, yes. 6 Q. Does it matter -- 7 A. There's different types of standards for 8 what is adulterated; but certainly, that could be, 9 yes. 10 Q. Do all CGMP violations result in a 11 product being adulterated? 12 A. I just said to you it depends. Again, 13 it's consistent with the definitions. In fact, the 14 letters that are -- have been issued in this case, 15 that talk about adulteration or being adulterated, 16 are linked to CGMP violations, but certainly there 17 are different types of CGMP violations that may or 18 may not result in a finding of -- issuing of a 19 warning letter that deems a product adulterated. 20 So it depends, that's what I'm saying to 21 you. It just depends. I'd have to look at each 22 situation. In this case, yes, the CGMP violations 23 are what is cited by FDA, as a basis for its finding 24 of adulteration and it points specifically to the 25 presence of the NDMA and NDEA impurities in the</p>	<p style="text-align: right;">Page 213</p> <p>1 A. I think that depends on the situation. 2 What type of impurity it was, is it a potent toxicant 3 or a genotoxicant, it's -- let's say, that's a 4 case-by-case question that you would need to answer 5 based on the situation in hand. 6 In this situation, indeed, that was an 7 issue. 8 Q. And when you say these are case-by-case 9 situations, is there some sort of FDA document that 10 sets out what the standards are and what the criteria 11 are for -- in other words, are your opinions based on 12 any sort of document, are they based on specific FDA 13 standards? What are your opinions based on that your 14 offering me right now? 15 MR. VAUGHN: Object to form. 16 A. Repeat your question again. But not the 17 question you just asked, the first question, I'm 18 sorry. 19 Q. I'm not sure what you mean by "repeat 20 your first question," I -- 21 A. You asked me a question, and I thought I 22 answered it, and then you asked a clarifying 23 question. So go back to the original question, and 24 let me make sure I am clear, I am certainly -- 25 because I think you're misunderstanding me because I</p>

<p style="text-align: right;">Page 214</p> <p>1 absolutely am saying that there are certain 2 standards. The question is, are there certain FDA 3 standards in terms of GMP violations where they talk 4 about the issues of seriousness and non-seriousness 5 of violations? There's a question-and-answer 6 document that's out there and a guidance document 7 talks about that, is that what you're asking me? 8 Q. I'm asking, is there a place I can go 9 for FDA regulations to understand your views about 10 when a CGMP violation results in adulteration? 11 MR. VAUGHN: Object to form. 12 A. You can go to my report and the actual 13 specific language and the definition of what's an 14 adulterated product, where it mentions that. So 15 that's on page -- 16 Q. That's not what I'm asking. 17 A. Yes, it is. You asked me for where you 18 go to, and time telling you, I lift it right out of 19 the definitional language of FDA for what's an 20 adulterated product, and it pounds on language around 21 good manufacturing practice. So that would be part 22 of my answer to you, and I'm looking for the section 23 of my report where I note that. 24 There, on page 25, I go to the law 25 itself, it's 21 U.S.C. 351, that talks about the U.S.</p>	<p style="text-align: right;">Page 216</p> <p>1 So I don't know what else to tell you, 2 and I think I actually, I've tried to give you a good 3 basis. The law is the founding for all regulations, 4 because the regulations are the codification of the 5 law. So that's why I started with the law, because 6 it's basic definition that links GMPs and 7 adulteration. 8 Q. Is it your opinion that every single 9 Valsartan pill manufactured with ZHP's API, after the 10 process change that we discussed earlier today, was 11 adulterated? 12 MR. VAUGHN: Object to form. 13 A. Has the potential to be adulterated, 14 yes. Unfortunately ZHP did not -- did not do 15 investigations and understand what was happening. 16 It's my opinion, however, as I state in my report, 17 that the presence of NDMA and NDEA could deem the 18 product adulterated. So therefore, any API or any 19 finished dose product containing those would indeed 20 be adulterated. So the fact that the process changed 21 was the result -- was what resulted in those 22 impurities. It makes all of those potential 23 adulterated product. 24 Q. Did FDA send any warning letters to ZHP 25 with respect to its CGMP practices regarding the</p>
<p style="text-align: right;">Page 215</p> <p>1 drug law that addresses what makes a drug 2 adulterated, and gives the definitions for it right 3 there. And I've highlighted some of it that I 4 thought was particularly -- at issue in this 5 particular case. It talks about conformity with good 6 manufacturing practice to ensure that the drug meets 7 the requirements as to safety and has the identity, 8 strength and meets the quality and purity 9 characteristics. 10 Q. Is this all the FDA documents that 11 you're relying on with respect to your opinion that 12 some CGMP violations lead to adulteration and some 13 don't? 14 A. No, there's warning letters on the FDA 15 database, when you do a search for adulteration, that 16 you'll find that the majority of the time, they are 17 citing to CGMP violations. There is -- there are the 18 guidance documents that talk about GMPs and what 19 particular parts of the GMPs exhibit and why. I 20 think there was a question-and-answer document. Yes, 21 there's a question-and-answer document that I cite in 22 my report called, "Questions and Answers on Current 23 Good Manufacturing Practice Requirements." And there 24 is a -- there are sections there that talk about 25 that, questions back and forth.</p>	<p style="text-align: right;">Page 217</p> <p>1 manufacture of Valsartan before 2018? 2 A. You said a warning letter? Is that what 3 you're asking? I don't believe a warning letter on 4 that issued before then, no. But they certainly 5 had -- the company had information before the FDA 6 warning letter came out about this problem. 7 Q. You testified that you did a hazard 8 assessment in this litigation, correct? 9 A. That's where I started, with the terms 10 of -- in terms of NDMA and NDEA. 11 Q. How many hours did the hazard assessment 12 take you? 13 A. Only five or six hours. I already had 14 knowledge of where to go to look in terms of sources 15 and resources, 'cause again I'm familiar with 16 nitrosamines and NDMA. So it wasn't difficult for me 17 to collect the -- I already had textbooks, for 18 example, that talk about the impurities, those 19 particular compounds, and their risks and their 20 hazards. 21 I also already had in my possession the 22 tox -- IARC document that I had from I don't know 23 which project several years back, but I had looked at 24 NDMA as an issue, not in a pharmaceutical case, but 25 in other contexts, so five to six hours to go through</p>

<p style="text-align: right;">Page 218</p> <p>1 those documents based on the fact that this was 2 something I had looked at before and I was very 3 familiar with what NDMA is, and what NDEA is. 4 Q. And you conducted a 5 weight-of-the-evidence methodology here, you 6 testified. How long did you spend on that? 7 MR. VAUGHN: Object to form. Misstates 8 prior testimony. 9 A. So I told you that, based upon my review 10 of the monographs, the authoritative sources, the 11 text books, I didn't go through every piece -- didn't 12 pull every piece of literature, but I used those as a 13 resource for my evaluation of hazard. So that 14 evaluation of hazard was weighing the information 15 that existed out there and the consistency of the 16 information is incredibly good. 17 There are no authoritative bodies that 18 say that they are not carcinogens. And no textbooks 19 that say they are not carcinogens, NDMA and NDEA. 20 Q. I think my question was just how many 21 hours did you spend on your weight-of-the-evidence 22 analysis? 23 A. That's something I can't give you an 24 exact time. I mean, the entire time I wrote my 25 report, I am weighing evidence based upon what I see,</p>	<p style="text-align: right;">Page 220</p> <p>1 weight-of-the-evidence approach to what I was looking 2 at. I'm trying to explain to you that in two 3 different parts of my report, there's different 4 methodologies that you may use. Weight of the 5 evidence is used for typically weighing scientific 6 information to come to some understanding of what 7 that scientific information says about the 8 relationship or the finding. 9 In this case, that was my five to six 10 hours I spent going through the authoritative 11 documents, looking at whether anything had changed 12 since the last time I looked at it in terms of the 13 cancer hazard, and whether or not NDMA and NDEA were 14 still identified as compounds that increase the risk 15 of cancer in humans, so that's what I told you was 16 five to six hours. 17 After that, the majority of the time on 18 this case was spent with reviewing evidence in the 19 case, going back to the regulatory language, the 20 guidance documents, and providing that discussion and 21 analysis. 22 Q. You said the last time you looked at it. 23 When was the last time you looked at NDMA and NDEA? 24 A. Before this case, probably about four 25 years ago.</p>
<p style="text-align: right;">Page 219</p> <p>1 what's available, what -- what evidence says on both 2 sides, either answer to my questions -- I don't come 3 in to the evaluation with a decision already made 4 about what my report is going to say, and my report 5 evolves as I review the information. 6 So weight of the evidence is, all of the 7 information is being weighed in terms of the -- the 8 evaluation of my report. 9 In regulatory, in the regulatory world, 10 when I am developing my regulatory opinions, the 11 process there is not the same. It's applying the 12 training, experience and understanding of the the 13 regulatory language, the guidance documents, the 14 things that there are, and whether or not what is 15 there is consistent with what the evidence tells you 16 in the case; statements by the company, warning 17 letters, official actions, what the labeling may say, 18 if it's a labeling issue. So that's a little 19 different. 20 Q. But you aren't able to tell me how much 21 time you spent in your weight-of-the-evidence 22 assessment? 23 A. I can't give you an exact number, no. 24 It's not like I sit and write down, "This day, we're 25 giving these documents," I applied only a</p>	<p style="text-align: right;">Page 221</p> <p>1 Q. And in what context were you looking at 2 that? 3 A. The context of an environmental 4 contamination issue. 5 Q. Can you explain? 6 A. It's a confidential project for a 7 client. So, no. I can't give you any more than 8 that. 9 Q. What were you doing for this client, 10 without identifying the client? 11 A. I was doing a hazard evaluation. The 12 presence of NDMA particularly, in the environment. 13 Q. And it's for litigation? 14 A. No, it's a consult project. 15 Q. Was it a pharmaceutical company? 16 A. No, it was not a pharmaceutical company, 17 the one I'm thinking about. 18 Q. Did you find any changes in the science 19 with respect to NDMA and NDEA between then and now? 20 MR. VAUGHN: Object to form. 21 A. Not with respect to the cancer hazard, 22 no. 23 Q. When you were doing that other project, 24 did you quantify any risk with respect to a dose of 25 NMDA?</p>

<p style="text-align: right;">Page 222</p> <p>1 A. No, this was another situation where the 2 issue was whether or not there was an -- an overall 3 risk associated with the presence of the contaminant. 4 And I'm going to call it "contaminant" here because 5 this is not a drug product. 6 Q. If you could turn to paragraphs 11 and 7 12 of your report. 8 A. Yes. 9 Q. Have you ever used these two paragraphs 10 in another expert report? 11 A. I'm thinking, only because I haven't 12 done that much generic drug work, so I'm thinking. I 13 might have used some of the information in -- in 14 paragraph -- the paragraph that's -- 24 for a project 15 that I worked on for a generic drug, yes, but it was 16 years ago. I haven't done a generic drug case in 17 quite, maybe six, seven years. 18 Q. I'm sorry, I was asking about paragraphs 19 11 and 12. 20 A. I thought you said pages 11 and 12, I'm 21 sorry. 22 Q. Okay. 23 A. Okay, we're talking past each other. I 24 have used very similar language to 11 and 12 in other 25 reports, yes, because I am often asked -- I have done</p>	<p style="text-align: right;">Page 224</p> <p>1 EXAMINATION (Cont'd.) 2 BY MS. MILLER: 3 Q. Dr. Plunkett, have you ever advocated 4 before a public agency on behalf of a company that 5 manufactured a product with genotoxic properties? 6 MR. VAUGHN: Object to form. 7 A. In California, is that what you're 8 asking? There's a California pesticide issue I 9 worked on, but I don't know that that compound -- it 10 wasn't NDMA, and it wasn't quite the same kind of 11 compound, but the issue was whether or not there was 12 a threshold for cancer there, based on it acting 13 through non-genotoxic methods. Is that what you're 14 asking me? 15 Q. I'm just asking you -- 16 A. Well, I did. I worked on a project for 17 a pesticide that was in California -- in California, 18 they have a -- the California agency that regulates 19 pesticides, outside of BPA, has under Part 65, has a 20 panel you can go before. There was a particular 21 pesticide that was acting -- wasn't a clear genotoxin 22 that was acting through potentially threshold 23 methods, and whether or not there was a cancer risk 24 that should allow the product to have to carry a 25 Part 65 warning, even though the product was marketed</p>
<p style="text-align: right;">Page 223</p> <p>1 many cases like this, where I'm asked to serve as a 2 regulatory expert or a toxicologist. And so the 3 methodology that I use is the same, whether it's a 4 consulting project, or a litigation project, for 5 example, with risk assessment. 6 And then I also am giving in paragraph 7 12 why it is that risk assessment is a methodology, a 8 weight-of-the-evidence as well, that makes sense to 9 use for answering questions in my area. 10 Q. So these two paragraphs were cut and 11 pasted from another expert report, correct? 12 A. I don't know about word for word, but 13 they are very similar, yes, because again, this -- I 14 get asked the kinds of questions I'm addressing here 15 in other cases in the past, yeah. 16 MS. MILLER: All right, let's go off the 17 record and take a break. 18 VIDEOGRAPHER: Going off the record, the 19 time is 4:39 p.m. Eastern Time. This is the end of 20 media unit 5. 21 (Recess taken.) 22 VIDEOGRAPHER: We're back on the record. 23 The time is 5:02 p.m. Eastern Time. This is the 24 beginning of media unit 6. 25 (Continued on following page.)</p>	<p style="text-align: right;">Page 225</p> <p>1 in the U.S. legally as a pesticide under EPA. 2 Q. Was that product genotoxic? 3 A. I'm just telling you now, it's operating 4 through a non-genotoxic mechanism. So there's 5 compounds that we understand, instead of causing 6 direct damage to DNA, may cause changes, for example, 7 in proteins that -- or signaling pathways that 8 control cell proliferation. And some of those 9 compounds at certain high doses, you can identify 10 that the signaling pathways overwhelm the normal 11 machinery of the cell such that you get uncontrolled 12 proliferation, so these are considered non-genotoxic 13 carcinogens. 14 And so in this case, that's not what 15 we're talking about, we're talking through genotoxins 16 that are acting through direct DNA damage, but not 17 genotoxic carcinogens, can be -- they have risks and 18 how they can be assayed differently based on the 19 mechanism and the mode of action. 20 Q. Have you ever done consulting work for a 21 company with respect to a product that was genotoxic? 22 A. At Environ it's possible, yes. There 23 might have been a product that had genotoxicity, an 24 industrial chemical project or -- not in the aspects 25 of the pharmaceuticals, no. Or -- you can assume --</p>

<p style="text-align: right;">Page 226</p> <p>1 even a consumer product other than a pesticide now, 2 that I can think of.</p> <p>3 Q. Have you ever advised a company to stop 4 manufacturing a product because you thought it was 5 genotoxic?</p> <p>6 A. I wouldn't have done it based upon just 7 genotoxic. We did advise companies, I had, when I 8 worked at Environ in particular, we advised companies 9 about cancer hazards for different kinds of products 10 and we would give them the advice that the product 11 had a hazard that either needed to be considered or 12 would affect the regulation of the product.</p> <p>13 But I can't think of one where I gave 14 advice just on genotoxicity because typically, for 15 products, you look beyond that and you look for a 16 genotoxic data backed up by animal data or some other 17 in vivo data, which is why this product, with these 18 products it's so important, because you have the 19 whole picture, you have the -- you have the in vivo 20 data to show that indeed, you can get beyond 21 genotoxicity to actual cancer.</p> <p>22 Q. Is it your opinion that every 23 genotoxic -- every product that contains genotoxins 24 should be removed from the market?</p> <p>25 A. I don't think I've formed that opinion,</p>	<p style="text-align: right;">Page 228</p> <p>1 for dummies so let me go there, where I describe the 2 two processes. Let me find it.</p> <p>3 On paragraph -- long paragraph, I 4 apologize for that -- starts on page 16, paragraph 5 28. And I go through the understanding and the 6 explanation about the -- about the TEA and the 7 process, and this actually deals with, in 2019 what 8 ZHP found with respect to the cause, and it -- and I 9 don't want to go into the detail, but essentially I 10 think those things are described there.</p> <p>11 Do you want me to read to the record or 12 just refer you to that paragraph? Because it talks 13 about the TEA process, it also talks about, I 14 believe, the zinc chloride process as well.</p> <p>15 Q. I'm sorry, what page are you on? I 16 don't see what you're referring to.</p> <p>17 A. Paragraph 28, the easiest way for me to 18 send you there. It starts on page 16, it goes 19 over -- I apologize, this is like a very unusual 20 paragraph for me. It goes on for two-and-a-half 21 pages, over to page 18.</p> <p>22 Q. Can you just point me to where it 23 describing how the NDEA was formed?</p> <p>24 A. So for the TEA, it comes on the 25 second -- the third page, 18. And it starts to the</p>
<p style="text-align: right;">Page 227</p> <p>1 no. Because it's very case-specific and 2 exposure-specific, and exposure-potential-specific.</p> <p>3 But certainly, there are cases of human 4 drug products, either prescription or over-the- 5 counter, the presence of genotoxicity as a hazard is 6 acceptable for things like cancer drugs, because of 7 the issue of the benefits so outweigh the risk. Many 8 cancer drugs actually have potential to initiate 9 cancer later in life if you're on them long enough.</p> <p>10 But generally, no. That would not be the case for 11 drugs or products you would want those drugs or 12 products to be not probable carcinogens, for example.</p> <p>13 Q. Dr. Plunkett, are you familiar with the 14 chemistry behind the TEA process and how that led to 15 the formation of NDEA?</p> <p>16 A. Only from some documents I've seen 17 describe it but again, that was beyond the scope of 18 my work. It was my understanding that the chemists 19 in the case would be handling the details on the 20 process and the -- and the steps in the process that 21 were readily identifying as posing a risk.</p> <p>22 Q. Can you explain for dummies how the NDEA 23 was formed?</p> <p>24 MR. VAUGHN: Object to form.</p> <p>25 A. So I have in my report the explanation</p>	<p style="text-align: right;">Page 229</p> <p>1 the top of the page, "N-Nitrosodiethylamine is 2 potential process-related impurity which has a 3 similar formulation mechanism as NDMA. It is most 4 likely generated in terminated TEA process with" -- 5 this is -- it's an acronym, "NaNO₂," which is sodium 6 nitrate, "quenching, in which TEA-HCl (containing 7 potential impurity of diethylamine) and nitrous acid, 8 exist simultaneously to render the nitrosation 9 reaction to proceed."</p> <p>10 Want to keep reading? I mean, this is 11 the paragraph I'm talking about.</p> <p>12 Q. What is this quoting from?</p> <p>13 A. Quoting from, starting back on page 17, 14 starts within 2019, this was ZHP's statements 15 regarding their investigation. So I'm referring to a 16 ZHP document, pointing to pages 932 to 933, last page 17 Bates.</p> <p>18 Q. Is it your opinion that it was known in 19 20123 that TEA could transform into diethyline under 20 conditions similar to those involved in the 21 manufacturing of Valsartan API, and that that could 22 then react to sodium nitrate and hydrochloric acid in 23 the quenching step to create NDEA?</p> <p>24 A. I don't think I ever formed the opinion 25 that all those specifics were taught in the</p>

<p style="text-align: right;">Page 230</p> <p>1 scientific literature. Instead, if you look at my 2 opinion or statements in my report about 2012, it's 3 teaching that N-nitrosamines, generally, are 4 potential products that can be produced during the 5 different processes. Again, for details on this, 6 Dr. Hecht, the chemist, has many pages in his report 7 where he discusses the -- these issues about the 8 chemical reactions and the foreseeability. 9 Q. As I recall, the literature you cited 10 was about the degradation of DMF. Did you cite any 11 literature identifying that TEA could transform into 12 diethylene that could react with sodium nitrate and 13 hydrochloric acid and that could lead to NDEA? 14 MR. VAUGHN: Objection to form. 15 A. I think I -- I don't believe -- I don't 16 believe I've cited in my report a specific document 17 that gives all those details. However, and that's 18 why I then pointed you to, first to Dr. Hecht, who 19 gives a very detailed description of it, and then 20 also the two sources of information that -- excuse 21 me -- were brought out in depositions. 22 Q. Were those two sources of information 23 related to DMF and NDMA? I'm asking about the TEA 24 process. Have you cited any literature that you 25 believe shows the foreseeability of NDEA developing</p>	<p style="text-align: right;">Page 232</p> <p>1 it is a guidance document so it doesn't surprise me 2 if it does, but as -- I think I covered this earlier 3 in the day with you in some detail. How, what 4 guidance means, and in my experience, what guidance 5 means to the industry that I have worked for. 6 Q. I think you said earlier, I believe you 7 said earlier today that there's language in the 8 introduction to these documents about them being only 9 guidance, but I don't believe you testified that 10 every single page has a header that says, "Containing 11 non-binding recommendations." 12 A. I don't think you asked that question. 13 So you know, I don't know if every single page does, 14 it's possible that they do, but regardless of whether 15 they are labeled on the document as nonbinding, they 16 are still very important documents in terms of what 17 industry should be considering and using in terms of 18 guidance as they develop their processes to ensure 19 that they have full compliance in terms of GMPs, but 20 have a adequate quality system as well for their 21 drugs. 22 Q. Just the term "nonbinding." 23 A. I think you asked me that before and I 24 think -- I think we agreed to the word 25 "recommendation," but I told you also that in my</p>
<p style="text-align: right;">Page 231</p> <p>1 as part of the TEA quenching process? 2 MR. VAUGHN: Object to form. 3 Argumentative. 4 A. So I would point you to the report of 5 Dr. Hecht, discusses the foreseeability issue with 6 these particular -- these particular processes. 7 Again, it -- that was not -- scope of my work did not 8 include doing what Dr. Hecht did. 9 Q. Are you familiar with M7? 10 MR. VAUGHN: Object to form. 11 A. As far as if -- by M7 you're talking 12 about the amendment to the ICH, is that what you're 13 talking about? 14 Q. "M7, Assessment and Control of DNA 15 Reactive Mutagenic Impurities in Pharmaceuticals to 16 Limit Potential Carcinogenic Risk, Guidance For 17 Industry," are you familiar with that document? 18 A. Yes, that's what I was referring to, 19 because it's tied to the ICH. 20 Q. It's about a hundred-page document, does 21 that sound about right? 22 A. I have no idea how many pages it is. 23 Q. Does the top of every single page say, 24 "Contains non-binding recommendations"? 25 A. I'd have to look, I don't know. Again,</p>	<p style="text-align: right;">Page 233</p> <p>1 experience, with guidance and similar documents like 2 the M7, that those indeed are guidance or 3 recommendations that industry implements in order to 4 comply with certain parts of their -- of the FDA 5 regulations or the need for produce a quality 6 product. 7 Q. You refer in your report to "ICH core 8 principles." Do you recall using that term? 9 A. I may have. I don't know. Possible I 10 did. 11 Q. Is there a document or literature that 12 lists what the ICH core principles are? 13 A. If I used the word, I should have had a 14 citation for it, so I need to look. Where are you 15 looking in my report? 16 Q. Well, you use it multiple times, but if 17 you look it -- at the top of page 31 you say, "ICH 18 core principles." And I just -- I just want to 19 know -- 20 MR. VAUGHN: Dr. Plunkett, take your 21 time to read the entire paragraph from your expert 22 report, starting on the page before. 23 MS. MILLER: I was not suggesting she 24 not do that, Brett. 25 MR. VAUGHN: I didn't say that you</p>

<p style="text-align: right;">Page 234</p> <p>1 suggested it, I was just --</p> <p>2 MS. MILLER: Okay. She asked me where</p> <p>3 she used the --</p> <p>4 MR. VAUGHN: You saw on the page before,</p> <p>5 and tell her the next one. I'm telling her to read</p> <p>6 the whole paragraph.</p> <p>7 A. So core principles would relate to the</p> <p>8 specific steps or criteria that are set out in the</p> <p>9 ICH guidelines, and that is indeed how I described</p> <p>10 them, bottom of page 30, I say -- I actually have the</p> <p>11 opinion that what Dr. Gu testified to, and I say,</p> <p>12 "Failed to apply core principles of the ICH</p> <p>13 guidelines related to identification of impurities."</p> <p>14 So for example, in the ICH guidelines,</p> <p>15 there's different things that are described in terms</p> <p>16 of quality, and one of them has to do with</p> <p>17 identification of impurities. There's other core</p> <p>18 principles that are also described and I'd have to</p> <p>19 pull the guidance documents out in order to list them</p> <p>20 all for you.</p> <p>21 Q. Do ICH documents have a section called</p> <p>22 "Core Principles"?</p> <p>23 A. I don't know. I don't recall. I'd have</p> <p>24 to go look.</p> <p>25 Q. How do I know in reading an ICH document</p>	<p style="text-align: right;">Page 236</p> <p>1 principles of labeling regulations. I mean,</p> <p>2 there's -- I think it's a common term used when</p> <p>3 you're talking about compliance and regulations.</p> <p>4 Q. Can you identify someone whom you've</p> <p>5 heard use that term?</p> <p>6 A. My business partner, Dr. Rudenko, who</p> <p>7 used to work for FDA, one of my other contractors in</p> <p>8 my business, Dr. Merker, who used to work at</p> <p>9 CFSAN.</p> <p>10 Q. I thought you said FDA speeches.</p> <p>11 That's --</p> <p>12 A. Well, she's -- she's given slide talks</p> <p>13 and presentations and I've seen her -- Larissa and I</p> <p>14 had a business relationship off and I since 1989.</p> <p>15 We've worked together three times. She went to FDA</p> <p>16 for 15 years, and while she was there, I used to hear</p> <p>17 her talks, go to her seminars, I've heard her do</p> <p>18 that.</p> <p>19 Dr. Merker recently retired. He still</p> <p>20 uses FDA lingo all the time. He talked about core</p> <p>21 principles of food safety assessment.</p> <p>22 So again, I think this is kind of an</p> <p>23 odd -- an odd argument we're having if it's an</p> <p>24 argument. I mean, to me, core principles has a</p> <p>25 special English language meaning. It's things that</p>
<p style="text-align: right;">Page 235</p> <p>1 what you mean when you say "core principles"?</p> <p>2 A. The things that -- what they outline as</p> <p>3 being important to compliance for quality. So they</p> <p>4 have certain things that they describe. The easiest</p> <p>5 way would be to pull the document up, if you want to</p> <p>6 do that. And you can see different sections or</p> <p>7 different discussion points. And impurities,</p> <p>8 identification of impurities in -- is one of those</p> <p>9 "core principles."</p> <p>10 I'm using the word "core principle"</p> <p>11 based upon my experience with, you know, referring to</p> <p>12 those. In terms of describing what they are. It's</p> <p>13 just like the regulations, the 21 CFR Section 210 and</p> <p>14 211, set out the core principles for CGMP, one for</p> <p>15 finished dose manufacturers on 211, and general</p> <p>16 principles or core principles also within</p> <p>17 Section 210. I'm not giving it any -- I'm not</p> <p>18 meaning to give it any special magical meaning, if</p> <p>19 that's what you're asking me.</p> <p>20 Q. Is the term "core principle" ever used</p> <p>21 by ICH or by the FDA?</p> <p>22 A. I have no idea. It's something that in</p> <p>23 the industry, and in my experience, I've heard people</p> <p>24 use many times. I've heard FDA people give lectures</p> <p>25 talking about the core principles of GMPs, core</p>	<p style="text-align: right;">Page 237</p> <p>1 are inherent to the system, be it a regulatory system</p> <p>2 that controls food safety, the regulatory system that</p> <p>3 controls all the drugs that must be adhered to.</p> <p>4 Q. When you talk about ICH core principles</p> <p>5 at the top of page 31, you mention, you write,</p> <p>6 "(e.g. ICH Q3A)".</p> <p>7 ICH Q3A provides guidance about</p> <p>8 impurities in new drug substances, correct?</p> <p>9 A. I'd have to pull it up, but I think it</p> <p>10 does.</p> <p>11 Q. Does ICH Q3A apply to changes in</p> <p>12 already -- to manufacturing changes to existing API</p> <p>13 products?</p> <p>14 MR. VAUGHN: Object to form.</p> <p>15 A. I would say that it does but I would</p> <p>16 neat to look to see if they exclude that. I don't</p> <p>17 recall that being excluded in the discussions of</p> <p>18 these types of principles. Regardless of whether</p> <p>19 you're making a change to an existing ANDA, it's a</p> <p>20 new process for making the drug. So certainly, those</p> <p>21 same principles or recommendations or guidelines</p> <p>22 would apply.</p> <p>23 Q. Are you familiar with any literature</p> <p>24 that you can cite to me saying that ICH Q3A would</p> <p>25 apply to manufacturing changes to existing API?</p>

<p style="text-align: right;">Page 238</p> <p>1 MR. VAUGHN: Object to form.</p> <p>2 A. I haven't look for that, so I can't</p> <p>3 answer that. I'd have to look, but also that</p> <p>4 question that I raised as I was doing my -- writing</p> <p>5 my report.</p> <p>6 Q. When did the FDA adopt ICH M7 as</p> <p>7 guidance?</p> <p>8 MR. VAUGHN: Objection, foundation.</p> <p>9 A. I believe it was in my report. I'm</p> <p>10 going to say 2016, but it was put forth publicly in</p> <p>11 2014.</p> <p>12 Q. Was ICH M7 adopted by the FDA before or</p> <p>13 after process changes at issue here?</p> <p>14 MR. VAUGHN: Objection, form.</p> <p>15 A. So I believe at least with one of the</p> <p>16 process changes it would have been after, but it</p> <p>17 doesn't matter because the M7 recommendations or</p> <p>18 guidelines or statements are essentially consistent</p> <p>19 with the 1999 ANDA guidance document by FDA -- that</p> <p>20 FDA put out when it talks about considering the issue</p> <p>21 of potent toxicants, or toxic compounds.</p> <p>22 Those are always part of the -- of</p> <p>23 the -- of the equation and impurities have been</p> <p>24 recognized as a potential issue to be addressed for</p> <p>25 compound -- for drug products for a very long time.</p>	<p style="text-align: right;">Page 240</p> <p>1 minor in your DMF or in your submissions to us, but</p> <p>2 yet you called it critical. Based on that, it's an</p> <p>3 important concern as well, the FDA, did.</p> <p>4 Q. Do you know what ZHP meant when it said</p> <p>5 "critical"?</p> <p>6 MR. VAUGHN: Object to form.</p> <p>7 A. I have no information to indicate that</p> <p>8 they meant anything other than important. "Critical"</p> <p>9 usually means important.</p> <p>10 Q. Do you have any reason to believe that</p> <p>11 ZHP's internal use of the word "critical" was</p> <p>12 intended to mean major under the FDA's --</p> <p>13 MR. VAUGHN: Object to form.</p> <p>14 A. If it's meant to mean major, to me, the</p> <p>15 important thing was not exactly how they classified</p> <p>16 it, even though FDA points to that issue. The issue</p> <p>17 for me is they made changes, didn't do a full</p> <p>18 assessment on the impact of those changes, even</p> <p>19 though those things indeed had important implications</p> <p>20 for the impurity profile of the drug.</p> <p>21 Again, this issue of major-minor</p> <p>22 critical changes, other experts in the litigation</p> <p>23 have a lot more to say about it than I do. I point</p> <p>24 to it mainly because of my opinions related to the</p> <p>25 fact that the product, FDA was recognizing that the</p>
<p style="text-align: right;">Page 239</p> <p>1 The language is a bit different, but that doesn't</p> <p>2 mean that there was no recognition of the need to</p> <p>3 know the potency or the toxicity of potential</p> <p>4 impurities.</p> <p>5 Q. You write in your report that ZHP's</p> <p>6 change to utilizing chloride and dimethylformamide</p> <p>7 was internally classified as a critical change, is</p> <p>8 that correct, do you recall that?</p> <p>9 A. There is a paragraph where I quote from</p> <p>10 either a document or a deposition, yes. And I -- if</p> <p>11 you show me where you are, and then I'll clear it</p> <p>12 somewhere else, but I do know that, yes.</p> <p>13 Q. Does the FDA use the term "critical</p> <p>14 change"?</p> <p>15 MR. VAUGHN: Object to form.</p> <p>16 A. In terms of their guidance on when to</p> <p>17 submit a supplement, is that what you're asking me?</p> <p>18 They use different language.</p> <p>19 Q. What languages does FDA use?</p> <p>20 A. It uses, the issues would be major</p> <p>21 versus minor, minor versus major changes. But</p> <p>22 regardless of that, FDA's warning letter points this</p> <p>23 out, I think that's where there discussion is, if the</p> <p>24 NDMA themselves points out to the company that you</p> <p>25 said something was minor, you said something was</p>	<p style="text-align: right;">Page 241</p> <p>1 company had serious concerns with GMPs and product</p> <p>2 quality. And one of the reasons -- one of the things</p> <p>3 I cite to was the fact that the company didn't share</p> <p>4 with FDA their exact descriptions of those process</p> <p>5 changes when they -- when they made them to the DMF.</p> <p>6 Q. Which description of the process change</p> <p>7 did ZHP not share with FDA?</p> <p>8 A. They didn't call it a critical change</p> <p>9 which would -- which were a different implication</p> <p>10 than a minor change.</p> <p>11 Q. But we just agreed that</p> <p>12 "critical change" is not an FDA terminology, right?</p> <p>13 MR. VAUGHN: Object to form.</p> <p>14 A. But "minor change" is. And if the</p> <p>15 company is distinguishing critical versus minor,</p> <p>16 which, if you read the deposition testimony, they</p> <p>17 indeed are, and then if you look at the FDA letter to</p> <p>18 the company, they indeed see that as an issue within</p> <p>19 the company as well.</p> <p>20 I'm just saying that, to me, that's</p> <p>21 evidence to show that FDA is recognizing that that</p> <p>22 was a consideration in terms of their decisions</p> <p>23 regarding the warning letter they issued and their</p> <p>24 decisions or their judgments regarding the lack of</p> <p>25 GMP compliance.</p>

<p style="text-align: right;">Page 242</p> <p>1 Q. I may have misunderstood your testimony 2 but I thought you testified that they didn't provide 3 the FDA with a complete description of the process 4 change. 5 Do you have reason to believe that ZHP 6 failed to provide the FDA with a full description of 7 what the process change was? Object to form? 8 A. That's not what I said. I said that 9 they didn't use the same language in their 10 description with FDA. They called it a minor change, 11 not a major change or a critical change, which is the 12 language they are using internally. 13 Q. Are there any internal -- 14 A. So -- 15 Q. -- are there any internal communications 16 where ZHP uses the term "major change"? 17 A. To FDA, ever? I didn't -- 18 Q. I said internal. I said are there any 19 internal documents where ZHP has referred to this 20 changes as a major change? 21 MR. VAUGHN: Object to form. 22 A. I didn't look for that, so I can't 23 answer that. I don't know. I think my mention of 24 this has to do -- that this issue in my report has to 25 do strictly with the discussion of the FDA findings</p>	<p style="text-align: right;">Page 244</p> <p>1 Q. Do you know what MSP is alleging in this 2 case? 3 MR. VAUGHN: Object to form. 4 A. No, I don't know what MSP -- I already 5 told you, you asked me questions and I haven't seen 6 the complaint, so if I haven't seen the complaint I 7 can't answer that. I guess maybe what I should tell 8 you to add to this answer, though, is that, I am 9 aware that the cases I'm working on, that there -- 10 that the Plaintiffs are alleging injuries of cancer 11 or fear of cancer related to their exposure to 12 Valsartan drug products. That I am aware of. But I 13 don't know what's in -- it's in the MSP complaint, 14 where that's even the same complaint, I can't answer 15 that. 16 Q. Were you retained for one specific case 17 or were you retained in the Valsartan litigation 18 generally? 19 A. I'd have to look at my confidentiality 20 agreement. I don't have a retainer or a contract. 21 I, right now I'm aware of a case, a Valsartan case, 22 that's this particular case that I'm working on, and 23 the issues that I'm addressing have to do with, it's 24 my understanding there are more than one Valsartan 25 case. But dealing with the toxicology, the hazard,</p>
<p style="text-align: right;">Page 243</p> <p>1 in the warning letter. The FDA themselves talks 2 about it. Other than, I do talk about the background 3 on what types of, how you classify certain changes 4 and whether you have to put in a pre-amendment 5 supplement, or whether you can put this in as a CBE, 6 or whether you can simply submit it as part of an 7 annual report. 8 Q. Do you compare ZHP's definition of 9 "critical change" with the FDA's definition of "major 10 change"? 11 A. Well, I lay that out on my report, no. 12 Again, that's something -- I've seen reports where 13 other experts in the litigation are doing some of 14 that. 15 Q. Do you know whether ZHP's internal 16 definition of "critical change" is the same as the 17 FDA's definition of major change? 18 MR. VAUGHN: Object to form. 19 A. I can't answer that without looking. I 20 don't know. I discuss this so if you need to see 21 what I said, I discuss this on pages -- in paragraph 22 27, paragraphs 14, 15, and then I talk about the 23 comment from FDA at paragraph -- right before 24 paragraph 28 on page 16. Rather a long paragraph, I 25 apologize.</p>	<p style="text-align: right;">Page 245</p> <p>1 the increased risk and then -- as I say in any 2 report, the general regulatory overview 3 responsibilities of a manufacturer and then my 4 analysis of what the evidence in the case says as it 5 relates to the regulatory requirements of a generic 6 drug company making either an API or a finished dose. 7 MS. MILLER: I think I'm close to the 8 end of my questioning. I need a break to confirm 9 that. So let's take five to ten minutes. Lee, could 10 you tell me how much time -- 11 VIDEOGRAPHER: Could we go off the 12 record, counsel? Going off the record. The time is 13 5:36 p.m. 14 (Recess taken.) 15 VIDEOGRAPHER: We are back on the 16 record. The time is 6:02 p.m. 17 MR. VAUGHN: Real quick, I just want the 18 record to reflect that we've had multiple breaks on 19 our own, and now we've been back for over ten minutes 20 waiting for it to start. Go ahead, Jessica. 21 EXAMINATION (Cont'd.) 22 BY MS. MILLER: 23 Q. Dr. Plunkett, you used to have a company 24 called Integrative BioStrategies, correct? 25 A. Yes.</p>

<p style="text-align: right;">Page 246</p> <p>1 Q. What happened to that company?</p> <p>2 A. When I took on my new business partner</p> <p>3 in January of 2020, in June of 2020, we decided to</p> <p>4 form a partnership and change the structure of the</p> <p>5 company so we were equal partners. So the ID was a</p> <p>6 company where I am -- I was the owner and my husband</p> <p>7 was an employee and Larissa originally, Larissa was</p> <p>8 working as an employee, but she and I are equal in</p> <p>9 terms of our business development.</p> <p>10 So we -- we formed a new company and, by</p> <p>11 doing that, we gave it a new name because we also</p> <p>12 started to have some new focuses to our business.</p> <p>13 Q. Does the new company have different</p> <p>14 employees from the old company?</p> <p>15 A. Yes.</p> <p>16 Q. Who has left and who has joined?</p> <p>17 A. So it's joining, so myself, I'm an</p> <p>18 employee, my husband is an employee still, he's still</p> <p>19 our -- administrative assistant, business manager;</p> <p>20 Larissa and I are joint partners in the company,</p> <p>21 fifty-fifty now, and her husband, who is also a Ph.D.</p> <p>22 physiology biochemist and also an employee of the</p> <p>23 company.</p> <p>24 Q. Were Larissa and her husband evolved in</p> <p>25 Integrative BioStrategies?</p>	<p style="text-align: right;">Page 248</p> <p>1 laws are more favorable to businesses here than they</p> <p>2 are in California.</p> <p>3 Q. Are you currently in your office?</p> <p>4 A. Yes.</p> <p>5 Q. And is your office in your home?</p> <p>6 A. Yes, it is.</p> <p>7 Q. When you --</p> <p>8 A. And hers is also in her home.</p> <p>9 Q. What's more favorable about Texas over</p> <p>10 California?</p> <p>11 MR. VAUGHN: Object to form.</p> <p>12 A. Taxes, regulation, and all the things</p> <p>13 you have to do in terms of businesses. That was the</p> <p>14 advice of our accountant, to incorporate in Texas</p> <p>15 instead of California.</p> <p>16 Q. Do you have a Twitter account?</p> <p>17 A. No. I do not like Twitter.</p> <p>18 Q. Has FDA ever asked you for your views on</p> <p>19 nitrosamines?</p> <p>20 A. No, not in the context of these issues.</p> <p>21 And I don't believe I've ever had a conversation</p> <p>22 where they have asked for it even, or ever over the</p> <p>23 years where I have worked in projects where FDA and I</p> <p>24 have interacted.</p> <p>25 Q. What percentage of your income last year</p>
<p style="text-align: right;">Page 247</p> <p>1 A. Her husband no. Her husband is new,</p> <p>2 he's only been around about two years. Initially, if</p> <p>3 you've ever read my depositions, in 2001, I joined</p> <p>4 Larissa, who was the original owner of Integrative</p> <p>5 Biostrategies, so she and I worked together from '01</p> <p>6 to '03. She left, went to FDA, and then I became the</p> <p>7 sole owner when she left.</p> <p>8 Q. The only new person that you haven't</p> <p>9 worked with before is her husband?</p> <p>10 A. Yes, that's correct.</p> <p>11 Q. And what's his name?</p> <p>12 A. His name is Austin Mirchelof.</p> <p>13 Q. Merchant, like the Merchant of Venice?</p> <p>14 A. No, M-i-r-c-h-e-l-o-f. He's a -- oh,</p> <p>15 gosh what's his background? It's like some kind of</p> <p>16 an Eastern European name, and I forget, I apologize,</p> <p>17 I've forgotten what it is.</p> <p>18 Q. And where is BioPolicy Solutions based,</p> <p>19 do you have an office?</p> <p>20 A. We have two offices, one in Houston,</p> <p>21 Texas here for me. We chose to have -- especially</p> <p>22 when we started the company in two 2020, it was</p> <p>23 advantageous. Her office is located in Ventura,</p> <p>24 California. We both have home-based offices. This</p> <p>25 company is incorporated in Texas because the -- the</p>	<p style="text-align: right;">Page 249</p> <p>1 came from litigation?</p> <p>2 A. Last year, about fifteen percent of my</p> <p>3 income. My -- our new company has had a real focus</p> <p>4 on regulatory, strategic planning, due diligence, and</p> <p>5 regulatory problem-solving for emerging companies</p> <p>6 using emerging technology.</p> <p>7 And during COVID, obviously, litigation</p> <p>8 slowed down a whole lot. Many of the cases I'm</p> <p>9 working on or have worked on are still pending,</p> <p>10 there's been a promise of trial for the last three</p> <p>11 years, nothing has happened. So...</p> <p>12 Q. How many hours would you say you spent</p> <p>13 in 2020 on litigation?</p> <p>14 A. I don't know. I'd have to go back and</p> <p>15 look at my records. I don't know. In 2020, it was</p> <p>16 very few.</p> <p>17 Q. I'm sorry, did I say 2020? I meant '22.</p> <p>18 But in 2022, 15 percent of your income was from</p> <p>19 litigation?</p> <p>20 A. Yes. About -- and it was actually about</p> <p>21 15 percent of my time because, unlike the old</p> <p>22 company, our rates for projects are the same</p> <p>23 regardless of whether it's a regulatory project or a</p> <p>24 litigation project. It's all charged at \$400 an</p> <p>25 hour.</p>

<p style="text-align: right;">Page 250</p> <p>1 Q. So can you estimate for me about how 2 much money you made from litigation last year? 3 A. I haven't done my taxes yet, so no, I 4 can't do that. Ask me in a couple of months, and I 5 maybe can tell. 6 Q. You said it was 15 percent. Don't yet 7 know about how much you earned last year? 8 A. Well, my personal income, and then there 9 is the income for the company, are you talking about 10 my personal income? 11 Q. Yes. 12 A. That 15 percent may not apply. I can 13 tell you much I make a year, I draw \$170,000 a year 14 salary. But the 15 percent number I'm giving you 15 would be the business billables overall in that 16 practice area, and some of that may have been Larissa 17 and some me. 18 Q. When you say you draw \$170,000, do you 19 also draw profits? 20 A. I can at the end of the year if there's 21 any money not distributed. We have more overhead now 22 because both Austin -- Dr. Mirchelof and my husband 23 are non-revenue-generating employees. They assist on 24 projects and we may charge Austin's time out, but 25 it's at a much lower rate.</p>	<p style="text-align: right;">Page 252</p> <p>1 litigations, what are those? 2 MR. VAUGHN: Object to form. 3 Dr. Plunkett, slow down just a little 4 bit so I can get the objections out. 5 THE WITNESS: I'm sorry. 6 MR. VAUGHN: Okay. 7 A. Active litigations would be this, this 8 litigation area, I'm active in the -- Valsartan, what 9 the other, oh, Taxotere, but theres' not a lot going 10 on there. I am getting ready for the Preservation 11 deposition, that litigation, some time in the spring. 12 I'm working in the -- one of the Ethicon Mesh 13 cases -- 14 MR. VAUGHN: I'm going to caution you to 15 not disclose any confidential information, 16 Dr. Plunkett. 17 A. Okay, all right. The other two things 18 I'm working on, I have not produced reports in yet, 19 so I guess that would be something I should wait 20 until I have produced a report. I assume that I will 21 be, you know, those will come to fruition but right 22 now, as far as active depositions or trials would be 23 Taxotere, and then this deposition here. 24 Q. So the other two are things that you 25 have not been disclosed as an expert yet?</p>
<p style="text-align: right;">Page 251</p> <p>1 Q. Do you know how much you personally 2 earned from -- do you know how much you personally 3 billed plaintiffs' lawyers for litigation in 2022? 4 MR. VAUGHN: Object to form. 5 A. I can't answer that, because it's too 6 early. Again, if you ask me that question in -- 7 after the tax season, I might be able to tell you. 8 Q. Do you know approximately how many 9 different cases you worked on in 2022? 10 A. You have my trial list. That tells you 11 how many depositions that I've been involved in. And 12 as far as cases, I'd have to look at my trial list to 13 see whether is it or isn't there. I mean, I have 14 maybe four active litigation areas. And then I have 15 two or three that are dormant. That I don't know 16 what's going to happen. But the top litigation is in 17 Bankruptcy Court, so who knows if that's going to 18 come back -- 19 Q. I'm a lawyer. 20 A. Okay, there you go. I have -- I've 21 still -- I still believe there's unresolved cases in 22 the IVC filter litigation, but I haven't been 23 approached with anything new in that in the last 24 eight to -- I would say the last year, actually. 25 Q. When you say you have four active</p>	<p style="text-align: right;">Page 253</p> <p>1 MR. VAUGHN: Object to form. 2 A. That's correct -- I'm sorry, that's 3 correct. Well, as far as I know, because the reports 4 haven't been -- I'm working on reports, but they have 5 not been completed. 6 Q. Who contacted you to request that you 7 serve as an expert in this litigation? 8 A. I don't know whether I first heard from 9 Mr. Vaughn or first heard from Mr. Nigh, both of whom 10 I, you know, encountered before. 11 Q. Where did you encounter Mr. Vaughn 12 before? 13 A. In a medical device litigation. It 14 sounds like maybe I shouldn't say. 15 MR. VAUGHN: You can answer which 16 medical device litigation, just don't comment on the 17 status of the litigation, please. 18 A. Oh, okay. In the hernia mesh 19 litigation, and then in the -- Mr. Nigh -- he and I 20 have crossed paths but I'm trying to think, I can't 21 think of the exact -- he's not been presenting 22 attorney with me, but he's been involved in different 23 cases I've worked on and I'd have to go back and look 24 at see where Levin Papantonio, the firm he was with, 25 was listed. It's possible that there was -- he was</p>

<p style="text-align: right;">Page 254</p> <p>1 listed in the talc litigation with me but I'm not 2 sure. 3 Q. Have you worked with Mr. Slater before? 4 MR. VAUGHN: Doctor, real quick, I also 5 want to caution you, do not disclose any 6 litigations in which you have not yet disclosed an 7 expert report. 8 MS. MILLER: She said she wasn't going 9 to -- 10 MR. VAUGHN: I'm sorry, she was going 11 kind of quick. I must have missed it. 12 Q. Have you come across Mr. Slater before? 13 A. In this litigation, I have. 14 Q. Is this the first litigation in which 15 you worked with Mr. Slater? 16 A. That I can recall. 17 THE WITNESS: And Mr. Slater, apologize 18 ahead of time if there've been other interactions. 19 Q. Nobody forgets Mr. Slater. Do you have 20 any other litigations you're working on with 21 Mr. Vaughn, other than medical device, hernia mesh, 22 and this one? 23 A. No, I don't believe so. 24 Q. Okay. You testified that only 15 25 percent of the revenues, I think, of BioPolicy</p>	<p style="text-align: right;">Page 256</p> <p>1 Q. Do you have additional unbilled time? 2 A. Just for this time in January getting 3 ready for the deposition. So no additional time on 4 reports. Obviously, you have my report, and this 5 time at deposition. 6 Q. How much time did you spend getting 7 ready for the deposition? 8 A. It's a guess, I haven't added it up for 9 January, I haven't done my billing, so I would say 10 another twelve, 15 hours, maybe. Twelve hours. 11 Q. And how much of that time was spent with 12 Plaintiff's counsel? 13 A. Probably half the time with Plaintiff's 14 counsel, and the other half on my own getting ready. 15 Q. Over the course of writing the report, 16 did you request additional documents from Plaintiff's 17 counsel that you hadn't received previously? 18 A. I requested additional documents when I 19 saw, for example, in deposition testimony, certain 20 area that I asked if there were additional documents 21 that might relate to that, yes. 22 I asked for, at one point, right towards 23 the end of the time I was preparing my report, I 24 asked if any of the other experts in the case for 25 Plaintiffs had reports ready. First Dr. Hecht did.</p>
<p style="text-align: right;">Page 255</p> <p>1 Solutions come from Plaintiffs' lawyers. What kinds 2 of clients constitute that other 85 percent? 3 MR. VAUGHN: Object to form. 4 A. Currently, in 2022, and 2021 as well, a 5 majority of them were either -- are either companies 6 that manufacture or make products or ingredients for 7 either the food industry, pharmaceutical industry, or 8 industrial industry as well as, because we work with 9 some enzyme manufacturers, and then we -- we also 10 work with -- do due diligence with investors at times 11 for review of technologies in the space of emerging 12 technologies, new ways to manufacture products that 13 haven't been implemented before. 14 And then the other work is, I still do 15 some patent work, putting together, doing 16 patentability evaluations, and strategy for taking an 17 invention for market with university-based inventors. 18 Q. Some invoices we saw, you've billed 19 about 150 hours since litigation, does that sound 20 right to you? 21 MR. VAUGHN: Object to form. 22 A. All in all, and throughout the work, 23 it's possible. I don't know, I didn't count it up. 24 I apologize. I probably should have done that but I 25 didn't.</p>	<p style="text-align: right;">Page 257</p> <p>1 I did see Dr. Bain's report, and Dr. Russ' report as 2 well, but those were all right before my report was 3 due. And then I -- I did ask them after I submit my 4 report, but I would obviously assume I would like to 5 see defense expert reports that overlapped my area if 6 they were in before my depo, and I was lucky enough 7 that a few of them were. 8 Unfortunately for me, they came in right 9 before Christmas, so it wasn't a whole lot of fun 10 working on them over Christmas, but I did review the 11 ones provided. 12 Q. Did you review drafts of the Bain or 13 Hecht reports before they were finalized and served? 14 A. No. I asked for final reports. I can't 15 tell you that I didn't see them at the same time they 16 were being served, the same day, but or -- but I 17 certainly saw what I consider final reports. 18 Q. Were they signed when you saw them? 19 A. Yes, they were. 20 Q. Are you relying on Dr. Bain -- I don't 21 know if she's a doctor. Are you relying on the Bain 22 or Hecht report ares in your opinions? 23 MR. VAUGHN: Object to form. 24 A. So I cite to Dr. Hecht as part of the 25 evidence for "foreseeability." I defer to him. But</p>

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<p style="text-align: right;">Page 258</p> <p>1 I'm not relying on him for any of the opinions 2 related to responsibility of the manufacturers or the 3 other general opinions in the regulatory area. 4 I also am not relying on him in terms of 5 my increased risk opinions, either. Those are 6 independent of, actually all of the other experts 7 that I've seen. I'm not relying on Dr. Bain, 8 although I have seen her report. And I did -- I 9 think I said to you a couple of times during the 10 deposition today that that's why I mentioned her. 11 Some of the questions you asked me are things that I 12 know are covered in those other expert reports. And 13 they were beyond the scope of some of the things that 14 I developed or was asked to do. 15 Q. Do you have an opinion as to whether 16 Dr. Hecht is more credible than ZHP's chemistry 17 expert, Dr. Xue? 18 MR. VAUGHN: Object to form. 19 A. I haven't formed an opinion comparing 20 them head to head in that way, no, I believe 21 Dr. Hecht, based on having seen his, I guess his CV 22 or resume that was attached to his report, and having 23 read his report, he certainly appears to be a 24 credible, competent, well-trained chemist. That's 25 all I can say. I mean, I don't try to compare the</p>	<p style="text-align: right;">Page 260</p> <p>1 it's -- again, I don't -- I don't -- I did not 2 consider his report when I developed my report, and 3 since I defer to Dr. Hecht, I paid a little more 4 attention to looking across his credentials and what 5 he was saying. 6 Q. You testified earlier that you have 7 represented companies before the FDA, is that 8 correct? 9 A. Yes, I've worked as a consultant to 10 companies and we've had meetings or I've helped them 11 respond to regulatory issues to the FDA. With the 12 FDA, yes. 13 Q. So on behalf of those companies, you've 14 had meetings with the FDA? 15 A. Yes. 16 Q. When was the last time you had a meeting 17 with the FDA? 18 A. Two months ago. 19 Q. And what was that with regard to? 20 A. It was with regard to safety assessment 21 for a new type of food produced by novel methods. 22 That's all I can say. 23 Q. Were you at the FDA for that meeting? 24 A. No, they were still doing virtual 25 meetings. I haven't -- I don't believe FDA has</p>
<p style="text-align: right;">Page 259</p> <p>1 quality of one expert versus the other. 2 Q. You have similar opinions with respect 3 to Dr. Xue? 4 MR. VAUGHN: Object to form. 5 Q. Have you read his CV report? 6 MR. VAUGHN: Object to form. 7 A. Can you spell that name that you gave 8 me? 9 Q. X-u-e. You said you had read his 10 report. We talked about it earlier. 11 A. A Defendants' expert or a ZHP witness? 12 Q. He's a chemist and you said earlier that 13 you had read his report. He's an organic chemistry 14 professor at the University of Maryland. 15 A. Oh, as -- that's what I'm asking you, as 16 an expert report? Is that what you're asking me? 17 Yes, I did. That's on my list of ones I had 18 reviewed. 19 Q. Correct. You testified that based on 20 Dr. Hecht's report and CV, you thought that he was a 21 credible chemist and I'm asking, did you reach the 22 same impression with respect to Dr. Xue? 23 MR. VAUGHN: Object to form. 24 A. Certainly, Dr. Xue has chemistry 25 credentials. I don't know what else to say, I mean,</p>	<p style="text-align: right;">Page 261</p> <p>1 resumed in-person meetings for normal interactions 2 yet. At least that was my understanding based upon 3 the last meeting we had. 4 Q. Have you had meetings at the FDA prior 5 to COVID? 6 A. Yes, I have. 7 Q. When was the last meeting you had at the 8 FDA itself? 9 A. It was not -- not over the phone. I'd 10 have to go back and look, I don't know. 11 Q. Which FDA office would that have been 12 in? 13 A. That one would have been -- oh, I know 14 which one it was, it was -- actually, the most 15 recent, I keep forgetting about this, the most recent 16 one would have been a meeting that FDA convened in 17 2020, right before the shutdown, on talc at the FDA 18 headquarters. That was the last in-person meeting I 19 went to. Before that, I'd have to go back and look, 20 it would have been probably six or seven years before 21 that easily. 22 Q. Were you invited by the FDA to that 23 meeting or was it open to the public generally? 24 MR. VAUGHN: Object to form. 25 A. It was a public meeting but you had to</p>

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<p style="text-align: right;">Page 262</p> <p>1 request an opportunity to speak, which I did. And I</p> <p>2 was accepted as a speaker at the meeting.</p> <p>3 Q. And what did you speak about?</p> <p>4 A. I spoke about the risks posed by talc</p> <p>5 particles and specifically issues related to</p> <p>6 elongated mineral particles, and the need to</p> <p>7 understand, as FDA at this meeting was trying to do,</p> <p>8 more about the toxicity of those particles as they</p> <p>9 related to the difference between different chemical</p> <p>10 makeups.</p> <p>11 So the issue is, the issue FDA was</p> <p>12 trying to address was, the chemistry may be different</p> <p>13 in terms of, say, fibrous talc versus asbestos</p> <p>14 fibers, but both fibers, depending on their shape and</p> <p>15 their physical form, pose a health risk.</p> <p>16 Q. Has FDA ever invited you to speak on a</p> <p>17 panel?</p> <p>18 A. No, not without being introduced through</p> <p>19 a client, no. Well, it was not -- when I've gone to</p> <p>20 speak to FDA, it's been being invited by the client</p> <p>21 to come and talk to the agency about an issue or a</p> <p>22 concern.</p> <p>23 Q. Do you have a template document you use</p> <p>24 to create litigation reports?</p> <p>25 A. Not a template, per se. I have certain</p>	<p style="text-align: right;">Page 264</p> <p>1 my background, what I was asked to do, and then I</p> <p>2 teach first, "Here's basic information," and then</p> <p>3 sometimes opinions are broken there, and sometimes</p> <p>4 they are set apart towards the end.</p> <p>5 Q. You talked earlier today about</p> <p>6 paragraphs 11 and 12. Do you remember what document</p> <p>7 you cut and pasted those from?</p> <p>8 MR. VAUGHN: Object to form.</p> <p>9 A. I didn't necessarily cut and paste them.</p> <p>10 Those are two paragraphs that I've had for a long</p> <p>11 time. I can't tell you when they would have last</p> <p>12 been used before I put them into this report. I'm</p> <p>13 trying to think what the last report before that</p> <p>14 would have been, and I don't know. I'd have to go</p> <p>15 back and look.</p> <p>16 Q. When you say you cut and paste them, do</p> <p>17 you type them in from scratch or did you copy them</p> <p>18 from another document?</p> <p>19 MR. VAUGHN: Object to form.</p> <p>20 A. Part of them are copied in, and then</p> <p>21 they are often rewritten a bit or edited a bit,</p> <p>22 depending on whether I'm doing a drug case or a</p> <p>23 device case, for example, or doing a cosmetic case,</p> <p>24 or doing -- they could be even different if I'm</p> <p>25 working on an environmental issue, so -- but those</p>
<p style="text-align: right;">Page 263</p> <p>1 parts of my expert reports that may look very similar</p> <p>2 from report to report, because, say for example if</p> <p>3 you look at the first few pages where I lay out my</p> <p>4 training and experience, I update that as I need to,</p> <p>5 but that would be very similar across different</p> <p>6 reports I prepare.</p> <p>7 Q. And so do you have one main document</p> <p>8 from which you cut and paste, or do you just cut and</p> <p>9 paste that from your most recent litigation report?</p> <p>10 MR. VAUGHN: Object to form.</p> <p>11 A. I've done different things depending</p> <p>12 upon the report that I'm dealing with, so not all my</p> <p>13 reports are set out with the same format. There are</p> <p>14 cases I work on where an attorney may ask me to use a</p> <p>15 format differently than I typically would. So for</p> <p>16 example, I don't always have a summary of opinions</p> <p>17 section or I don't always have large chapters, but I</p> <p>18 break my report up into opinion statements and go</p> <p>19 through them that way.</p> <p>20 So it's been different formats depending</p> <p>21 upon the need of the case or the desires of the</p> <p>22 client I'm working with, or my desire to teach a</p> <p>23 topic in a certain way.</p> <p>24 And I usually start, that's the one</p> <p>25 thing I usually do, I usually start my reports out,</p>	<p style="text-align: right;">Page 265</p> <p>1 basic parts, 11 and 12, where I lay out methodology</p> <p>2 or descriptions, that's something that I would expect</p> <p>3 to see in an expert's report. And I -- and so as a</p> <p>4 result, I typically include them.</p> <p>5 Q. I understand. I'm just asking where you</p> <p>6 copied it from.</p> <p>7 MR. VAUGHN: Object to form,</p> <p>8 argumentative.</p> <p>9 A. I told you, I don't know. Because I</p> <p>10 don't know what the last time I -- it's possible it</p> <p>11 was the last time I had written a report before this</p> <p>12 report or it may not be then. I don't know. I can't</p> <p>13 tell you that off the top of my head.</p> <p>14 Each report I write is a living</p> <p>15 document, so I don't do multiple drafts. I have a</p> <p>16 draft, it becomes a final report over the evolution</p> <p>17 of the document and I take notes when I'm writing,</p> <p>18 when I'm reading a document and that that evolves</p> <p>19 into a written paragraph.</p> <p>20 Q. Do you know whether Mr. Vaughn has ever</p> <p>21 referred you to other Plaintiffs' lawyers?</p> <p>22 A. I have not asked him that. I don't</p> <p>23 know. I assume he may have. I don't know.</p> <p>24 Q. Do you often get referrals from one</p> <p>25 Plaintiff's lawyer to another?</p>

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<p style="text-align: right;">Page 266</p> <p>1 A. Well, I often do. And that's because</p> <p>2 I'm very selective over the attorneys that I work</p> <p>3 with. I don't take all the cases that come to me.</p> <p>4 And I typically will not work for attorneys that I</p> <p>5 don't know. So if it's a reference, that gives me</p> <p>6 some comfort if the person who is referring is</p> <p>7 somebody that I trust. It's really important to me</p> <p>8 that I worked with attorneys that respect me, but</p> <p>9 also they are going to respect my standards and the</p> <p>10 way that I believe the work needs to be done.</p> <p>11 Q. Okay. I'm going to mark Exhibit 10.</p> <p>12 EXH (Plunkett Exhibit 10, invoice dated</p> <p>13 December 2022 on BioPolicy Solutions letterhead,</p> <p>14 addressed to Pendley, Baudin & Coffin, marked for</p> <p>15 identification, as of this date.)</p> <p>16 MS. MILLER: What page is that? I'll</p> <p>17 just -- we are just running short on time.</p> <p>18 We're going to introduce as Exhibit 10</p> <p>19 your invoices. Alex, are they on one document?</p> <p>20 A VOICE: Yes.</p> <p>21 MS. MILLER: Okay. I think all your</p> <p>22 invoices are on one document that Alex is going to</p> <p>23 put in the share drive that Adam doesn't like, so we</p> <p>24 can also put them up on the screen.</p> <p>25 Q. Do you recall when you submitted your</p>	<p style="text-align: right;">Page 268</p> <p>1 possession. I don't know that the 19th, that's</p> <p>2 possible, that I had some defense expert reports</p> <p>3 then. I don't recall what date those were sent over.</p> <p>4 Q. So that's just an error, you're saying,</p> <p>5 the part that says "report preparation."</p> <p>6 MR. VAUGHN: Object to form.</p> <p>7 A. Yes. Because my report was filed the</p> <p>8 date of it, I believe, I can check again but I'm</p> <p>9 pretty sure it's October 31st, yes. I haven't -- I</p> <p>10 have not produced -- if you're asking me have I</p> <p>11 prepared an additional report, no, I've not.</p> <p>12 Q. Okay. We also have this invoice that</p> <p>13 just says six hundred dollars with no itemization, do</p> <p>14 you know what it's for?</p> <p>15 A. It's for time that I spent working on</p> <p>16 the project. I don't know.</p> <p>17 Q. Was that sent --</p> <p>18 MR. VAUGHN: I'm sorry, could I hear</p> <p>19 that question?</p> <p>20 Q. Was that for the MSP matter?</p> <p>21 A. I have to go back and look at -- I have</p> <p>22 to go look for additional detail. If this is what it</p> <p>23 says, this is, I believe this may have been an</p> <p>24 invoice that was lost in the shuffle. What was the</p> <p>25 invoice before this one, can you show me? 'Cause I</p>
<p style="text-align: right;">Page 267</p> <p>1 report in this case?</p> <p>2 A. October 31st, I believe, 2022.</p> <p>3 Q. Do you know why your December invoice</p> <p>4 says, "Review of documents and report preparation"?</p> <p>5 A. No. It shouldn't. That's a mistake.</p> <p>6 Certainly, I was reviewing documents and that should</p> <p>7 be deposition preparation.</p> <p>8 Q. So did you begin --</p> <p>9 MR. VAUGHN: Are you still putting this</p> <p>10 up into the share file? I'm not able to access this</p> <p>11 one yet. Can -- I need to have a document if I'm</p> <p>12 going to defend.</p> <p>13 MS. MILLER: I know but I'm not talking</p> <p>14 about the document just yet. I'm just asking general</p> <p>15 questions.</p> <p>16 Q. Were you preparing for your deposition</p> <p>17 in December?</p> <p>18 A. Yes, I started preparation for my</p> <p>19 deposition in December because the date was set in</p> <p>20 December, I believe. I don't know which day it was</p> <p>21 set, but certainly there were -- so for example, also</p> <p>22 when I say review of documents here, part of this</p> <p>23 time in 27th, 28th and 29th, that would have been</p> <p>24 reviewing of defense expert reports as well, because</p> <p>25 that's the time period where I had those in my</p>	<p style="text-align: right;">Page 269</p> <p>1 don't have this file. The invoice before was August</p> <p>2 of 2022.</p> <p>3 Q. No, this was 2021, right. Is this an</p> <p>4 early invoice from 2021? This is the only invoice we</p> <p>5 got from 2021?</p> <p>6 A. You got every invoice that I have sent</p> <p>7 in litigation, so this would have been additional --</p> <p>8 this would have been additional work having</p> <p>9 conversations with attorneys at the start of my</p> <p>10 engagement. So it's -- this would have been, I would</p> <p>11 assume the time when I would have been first provided</p> <p>12 and agreed to be engaged in the project, so probably</p> <p>13 phone calls. But -- which would have been maybe -- I</p> <p>14 don't know whether it was an hour -- just a second,</p> <p>15 let me check something for you.</p> <p>16 (A pause in the proceedings.)</p> <p>17 Q. Just to make sure I understand, from</p> <p>18 February 2021 'till May 2022, you didn't do anything</p> <p>19 in this case?</p> <p>20 A. Nothing that I charged for, that's</p> <p>21 correct. You have everything that I charged for.</p> <p>22 And I was awaiting some materials, I do know that.</p> <p>23 But that's all I can tell you.</p> <p>24 Q. Stanley Baudin?</p> <p>25 A. He is at the law firm -- PBC law, and I</p>

<p style="text-align: right;">Page 270</p> <p>1 was told that was -- PBC law firm, again, I don't 2 know the -- Mr. Baudin, I don't know the -- what the 3 initials stand for, but this is where I was told to 4 send billing. 5 Q. Have you worked with him before? 6 A. I've been on a phone call where he's 7 been on before, but my principle contacts in the 8 litigation were Mr. Vaughn and Mr. Nigh, and then 9 Mr. Slater was on some of the phone calls as well. 10 Q. Have you worked with Mr. Vaughn in prior 11 litigation? 12 A. I don't believe -- well, I don't recall 13 the name from prior litigation, no. And again, 14 Mr. Vaughn is on the phone, I apologize if I'm 15 misremembering. 16 Q. Do you remember applying to serve on a 17 hydraulic fracture advisory panel in 2012? 18 MR. VAUGHN: Object to form. 19 A. No, not a hydraulic fracturing advisory 20 panel, no. I don't recall that. 21 Q. Do you recall giving a presentation on 22 September 23rd, 2022 entitled "Expert Witness 23 Testimony and Ethics, Science Over Advocacy"? 24 A. In September? 25 Q. Um-hum.</p>	<p style="text-align: right;">Page 272</p> <p>1 limitations of your work? 2 A. Yes. 3 MR. VAUGHN: Objection to form. 4 A. I probably did. 5 THE WITNESS: I'm sorry, Brett. 6 MR. VAUGHN: Slow down a little bit. 7 A. I probably did. I'd have to go back -- 8 I mean, I might still have the slides for that. I'd 9 have to go back and look at what I said. 10 Q. What would that mean? 11 MR. VAUGHN: Object to form. 12 A. Well, as a scientist, any time you're 13 working, be it in the legal arena, or the regulatory 14 arena, or just as an academic scientist, when you are 15 developing -- you're studying something or your 16 testing something or developing an opinion or a 17 conclusion or you're drawing conclusions about a body 18 of science, you need to consider the information that 19 you're looking at and whether or not there's any 20 limitations to that information as it was gathered 21 that would affect conclusions you might draw. 22 So for example, in the legal space, the 23 limitations that you would look at, for example, if 24 you were doing causation assessment, would be whether 25 or not, for example, you have been able to draw</p>
<p style="text-align: right;">Page 271</p> <p>1 A. Oh, yes, yes, yes, I'm sorry. I am so 2 sorry, it's getting late. Yes, I participated in a 3 webinar that was put on by the Society of Toxicology, 4 a special section called Ethical, Legal -- "Ethical 5 Legal Societal Issues," and it's a special section 6 that brings together people with interest in science 7 ethics, also in legal issues, and also in issues 8 related to societal change that are potentially 9 impacted by the regulations that are developed for 10 different kinds of products that have toxic effects. 11 So -- 12 Q. Were there any attorneys at this 13 presentation, at that webinar? 14 MR. VAUGHN: Objects to form. 15 A. Well, I do not know. It was an SOT. It 16 was an internal seminar for the Society of Toxicology 17 in cooperation with -- cosponsored by the -- another 18 specialty section called Sustainable Chemicals, so I 19 would be surprised if there was anybody from outside 20 SOT. 21 I can't tell you that there weren't 22 lawyers on the call because some SOT members have law 23 degrees as well. 24 Q. Do you recall saying in that 25 presentation that it's important to address the</p>	<p style="text-align: right;">Page 273</p> <p>1 conclusions based on a full array of data, human 2 experience, animal studies, in vitro study, and to be 3 able to look at not only just at the link that may 4 have been shown by epidemiology or observational 5 experience or clinical trials, but whether or not 6 there is a mechanism or a biologic link that you can 7 understand so you know why it is that the -- these 8 two things may be associated, this injury or this 9 effect with this particular exposure. 10 A lot of what, in this case, is within 11 the IARC document, is a good discussion of the 12 limitations of the different bodies of evidence and 13 the individual studies. So that's the kind of thing 14 you do as a scientist, you look at what's reported, 15 but also any of the strength and weaknesses of the 16 potential pieces of information that you apply. 17 Q. Do you anywhere -- is there any place in 18 your expert report here where you list what the 19 limitations are of your opinions? 20 MR. VAUGHN: Object to form. 21 A. I don't discuss specifically the 22 limitations on my opinions, but certainly, the 23 limitations on my opinions are based upon what it is 24 that I say and what I don't say. And then in 25 addition to that, based upon the type of evidence</p>

<p style="text-align: right;">Page 274</p> <p>1 that I cite to, in order to support those opinions.</p> <p>2 In the regulatory world, it's a little</p> <p>3 different than in the basic science world in terms of</p> <p>4 how you would discuss limitations. When I described</p> <p>5 to you a few minutes ago, when you talked about IARC,</p> <p>6 that's kind of a traditional application of</p> <p>7 discussion and limitations that are applied to the</p> <p>8 individual pieces of science.</p> <p>9 In the regulatory world, the issue that</p> <p>10 you would come to on limitations is whether or not</p> <p>11 you have training and experience and/or whether or</p> <p>12 not you have been able to identify specific</p> <p>13 regulations or specific standards that you could</p> <p>14 apply to answering questions that you're trying to</p> <p>15 answer or opinions that you're going to reach about</p> <p>16 conduct, responsibility, and what the data says.</p> <p>17 It's not quite the same as the</p> <p>18 discussion of limitations that I would have presented</p> <p>19 in that seminar.</p> <p>20 Q. Your seminar was about being an expert</p> <p>21 in litigation, right?</p> <p>22 MR. VAUGHN: Are you done with this</p> <p>23 exhibit yet? In so, can we take it down?</p> <p>24 MS. MILLER: Sure.</p> <p>25 MR. VAUGHN: Thank you.</p>	<p style="text-align: right;">Page 276</p> <p>1 overreach based upon the -- for example, if you're</p> <p>2 looking at a scientific article, making sure that you</p> <p>3 have considered evidence on both sides; are there</p> <p>4 papers that teach one thing, and papers that teach</p> <p>5 the other. So that's what I was talking about, being</p> <p>6 aware of your limitations. Not everybody can do</p> <p>7 everything.</p> <p>8 Q. I just wanted to know if there's</p> <p>9 anyplace in your report where you list limitations.</p> <p>10 MR. VAUGHN: Objection, asked and</p> <p>11 answered.</p> <p>12 A. I answered that at the very beginning,</p> <p>13 and then you asked me so some additional questions,</p> <p>14 so I apologize. I did start, I believe, by answering</p> <p>15 that question.</p> <p>16 Q. Somehow I missed the answer in your</p> <p>17 colloquy, but can you just tell me, is there anyplace</p> <p>18 in your report where I can go and see what the</p> <p>19 limitations are?</p> <p>20 MR. VAUGHN: Objection, asked and</p> <p>21 answered.</p> <p>22 A. I started out by telling you that there</p> <p>23 is not a specific section on limitations in that way.</p> <p>24 However, when I was describing where you can find</p> <p>25 my -- where I set forth my methodology, my training</p>
<p style="text-align: right;">Page 275</p> <p>1 Q. Your seminar was about being an expert</p> <p>2 in litigation, correct?</p> <p>3 MR. VAUGHN: Object to form.</p> <p>4 A. It was talking about an expert in</p> <p>5 litigation, and so that's a different area. So --</p> <p>6 that I didn't touch on that I can described for you.</p> <p>7 So in that seminar, we talked a little bit about</p> <p>8 staying in your lane, and that's what I was</p> <p>9 describing in my regulatory opinions.</p> <p>10 It's the idea you need to understand</p> <p>11 what your training, experience, and the science can</p> <p>12 allow you to do in terms of providing expert</p> <p>13 opinions, and especially with the specific of</p> <p>14 training and experience. So for example, what it</p> <p>15 is -- what can you say or what can you analyze based</p> <p>16 on that training and experience? Is it sufficient to</p> <p>17 allow you to draw conclusions?</p> <p>18 And so that's one of the things I spend</p> <p>19 a lot of time considering when I agree to take a</p> <p>20 case, looking at what are the issues, how could I fit</p> <p>21 in, are there things that are being addressed in this</p> <p>22 case that fit my training and experience, or not.</p> <p>23 And that's how I would approach, and I</p> <p>24 talked to you a little about bit about that in the</p> <p>25 seminar, stay in your lane, making sure not to</p>	<p style="text-align: right;">Page 277</p> <p>1 and experience, and that is a description of what --</p> <p>2 why it is I believe I can opine on certain areas.</p> <p>3 And then of course those judgments would be made, I</p> <p>4 understand the courts will make certain judgments</p> <p>5 based upon, you know, what that training and</p> <p>6 experience and analysis is.</p> <p>7 Q. You also stated in your presentation</p> <p>8 that it's important to acknowledge your biases, do</p> <p>9 you recall saying that?</p> <p>10 MR. VAUGHN: Objection, lack of</p> <p>11 foundation.</p> <p>12 A. I possibly did. I don't remember the</p> <p>13 context but I possibly did, yes.</p> <p>14 Q. Does this sound familiar, "You also need</p> <p>15 to acknowledge your biases. We all know that we have</p> <p>16 biases. I have biases as a scientist." Do you</p> <p>17 recall saying that?</p> <p>18 MR. VAUGHN: Lack of foundation.</p> <p>19 A. I don't recall that but certainly yes,</p> <p>20 I --</p> <p>21 Q. What are your biases?</p> <p>22 A. So --</p> <p>23 MR. VAUGHN: Object to form. Slow down</p> <p>24 just a little bit.</p> <p>25 Sorry, Dr. Plunkett.</p>

<p style="text-align: right;">Page 278</p> <p>1 A. So bias is that everybody, everybody, 2 based on your background and your experience in life, 3 has -- you see things a certain way. So for me, I 4 may, people may consider that I have a bias when I 5 read a paper if I had funding from industry. So 6 acknowledging bias in publications would be 7 acknowledging any potential conflicts or sources of 8 funding for your work, and that can -- because that 9 can indeed be seen as a potential bias.</p> <p>10 If all you ever do is work for industry, 11 there may be certain biases you have because you've 12 never seen things, for example, from the regulatory 13 side, or from the academic side or some other way to 14 look at an issue.</p> <p>15 I've been very lucky, I believe, in my 16 training and experience, that I started out at 17 Environ and I was introduced to litigation solely 18 from the defense side. I went out on my own. I did 19 some work in both areas, and now I do a lot of work 20 in drugs and FDA-regulated products from the 21 Plaintiff's perspective.</p> <p>22 But I believe that, based upon that 23 training and experience I had at Environ, that I can 24 see things from both sides. It's one of the reasons 25 I still work as a regulatory consultant, because I</p>	<p style="text-align: right;">Page 280</p> <p>1 solely based on what their experience is, and I was 2 telling you that I believe I've been fortunate in 3 that I've been able to have experience in more than 4 one world. So I've had academic experience, I've had 5 government research experience, I've had consulting 6 solely with industry, and I've had experience working 7 for nonprofit, as well as working in the litigation 8 area for injured parties.</p> <p>9 So that, to me, I think, gives me a 10 different view than someone who only ever does the 11 same thing. But certainly, when I said everybody has 12 biases, I mean, I have a bias probably in that I've 13 never been homeless, I've never had to worry about 14 where my next paycheck is coming from; so, if you 15 were to have a conversation and approach me, I might 16 have a bias that's related to that.</p> <p>17 I may have a bias because of being a 18 wife and an American woman. There's biases that come 19 into play with that. There is gender bias, there's 20 all kinds of sources of bias. And to me it's just 21 recognizing that bias is a potential issue you need 22 to consider.</p> <p>23 So when I approach problems, and I 24 approach a case, one of the ways I try to avoid bias 25 in a litigation world is, I try to approach this, a</p>
<p style="text-align: right;">Page 279</p> <p>1 think it's really important to be able to keep your 2 experience and your interactions in a way that you're 3 never seen as just doing this one thing or that one 4 thing. So that's -- that's one of the areas of bias.</p> <p>5 The other bias that sometimes comes into 6 play is whether or not, when you design studies, so 7 this came about, this comes about when you actually 8 talk about putting together say, a clinical trial, or 9 an animal study, there's -- may be bias in the way 10 the study is designed.</p> <p>11 So as a scientist, you need to consider 12 that because we may not want to design a study to 13 answer a question -- we should always design a study 14 in the best way to answer the question, rather than 15 being prevented from answering the question.</p> <p>16 And I believe that was a question that 17 came up during the seminar when we talked about study 18 design.</p> <p>19 Q. Okay. You just gave me examples of 20 theoretical biases and biases you don't have. But my 21 question was, what are your biases, do you believe 22 you have any biases?</p> <p>23 MR. VAUGHN: Object to form, asked and 24 answered.</p> <p>25 A. I believe that everybody has a bias</p>	<p style="text-align: right;">Page 281</p> <p>1 case in the litigation world, just the way I approach 2 a case when I give advice to my regulatory clients.</p> <p>3 Q. You said at your presentation that your 4 bias is as a scientist. Were you referring to bias 5 as a white female, to bias as never having been 6 homeless, or were you referring to other types of 7 biases?</p> <p>8 MR. VAUGHN: Objection to form, 9 argumentative, lack of foundation. You may go ahead, 10 Dr. Plunkett.</p> <p>11 A. So I don't recall the detail, but I'd 12 have to look at my slides. But certainly, a bias as 13 a scientist works would be, a scientist has a certain 14 way of looking at something, right? I have training, 15 I'm a pharmacologist and toxicologist, so I 16 approached my problem that way. I'm not a social 17 scientist, so I may have a bias towards expecting to 18 see certain kinds of information, statistical 19 analysis, where somebody else might come at the 20 problem and not feel those things are so important.</p> <p>21 So I don't recall -- I mean, if you have 22 the slides in front of you, we can talk about it. I 23 just don't recall the details of the talk. I really 24 don't.</p> <p>25 Q. Do you ever have preconceived notions</p>

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<p style="text-align: right;">Page 282</p> <p>1 about litigation when you're asked to -- when you are 2 being retained by a Plaintiff's lawyer, do you ever 3 have preconceived notions or ideas about litigation 4 before you accept a retention? 5 MR. VAUGHN: Object to form. 6 A. I certainly attempt to not bring any 7 information that I may or may not be aware of to the 8 table when I make that decision. Decisions I make on 9 whether to work in the litigation area have more to 10 do, not with the preconceived notion but with the 11 information that I know is available that I believe I 12 can or can't support. 13 But certainly, for example, in a case 14 like this, I was aware already of NDMA, so for 15 example, I certainly had an opinion that NDMA is a 16 carcinogen, before the -- before I entered this 17 litigation. However, that doesn't mean that I didn't 18 revisit that opinion by looking across, as I told 19 you, looking across what authoritative bodies and 20 textbooks have shed over the years, how far back in 21 time that went. 22 So that was a new analysis that I did 23 that wasn't just related to the fact that I was aware 24 that NDMA was a prototypical positive control used in 25 animal studies for cancer, which is something that</p>	<p style="text-align: right;">Page 284</p> <p>1 EXAMINATION BY 2 MR. HARKINS: 3 Q. Hi, Dr. Plunkett, this is Steve Harkins 4 with Greenberg Traurig for the Teva defendants, can 5 you hear me? 6 A. I can. Nice to meet you. 7 Q. Nice to meet you, too. You've been 8 going for a little bit. I'm happy to just continue. 9 I just wanted to check and make sure you don't need a 10 second for a break or anything, right? 11 A. Let's Keep going. 12 MR. VAUGHN: Thanks, Steve. 13 Q. All right. So Dr. Plunkett, I represent 14 Teva and obviously you're familiar with Teva and 15 their role in this case as a finished dose 16 manufacturer, right? 17 A. Yes. 18 Q. And because we don't have a lot of time 19 left, I just want to be clear, what I'm focused on 20 and what I'm going to be asking you questions about 21 is whether you have or have not formed opinions about 22 the conduct of the finished dose manufacturers in 23 this case, okay? 24 A. Okay. 25 Q. It appears that your report is pretty</p>
<p style="text-align: right;">Page 283</p> <p>1 I've been aware of since I was in academics in the 2 '80s. 3 Q. Do you ever accept a legal case because 4 you have preconceived notions about the substance of 5 litigation? 6 MR. VAUGHN: Object to form. 7 A. Not in a brand new area, no. Certainly 8 if I was approached by a lawyer that had a case 9 related to ovarian cancer and talc, I've done so much 10 work and analysis in that area that certainly I have 11 very strong opinions about the risks, but also what 12 the labeling for the product should have been over 13 time. 14 So I would bring that same view, unless 15 new information came about to change it, I certainly 16 would look for that, so even though I already have 17 that opinion, but that's -- that's a little 18 different. That's -- preconceived notions to me 19 would be more about the issue of the first time you 20 think about a problem, not the same problem that's 21 being presented to you again in the same way. 22 Q. Okay. 23 MS. MILLER: I don't have any further 24 questions. 25 (Continued on following page.)</p>	<p style="text-align: right;">Page 285</p> <p>1 focused on ZHP and while there are citations to Teva 2 documents, there are not a whole lot of references 3 directly in the narrative to Teva or Torrent, is that 4 fair? 5 A. That's probably true. 6 MR. VAUGHN: Object to form. 7 A. It's probably true that there aren't 8 many citations to just Torrent, many citations to 9 just Torrent, for example, or just Teva documents, 10 that's true. And the majority, if not all of the 11 company testimony, were ZHP employees, I believe, 12 that I've looked at so far. Maybe there was a Teva 13 or a Torrent person; but the majority of them -- 14 because the facts in this case, you -- Teva, not you, 15 but Teva as a company was using API manufactured from 16 ZHP, so a lot of the information, and I think I 17 mentioned them a couple of times today, in terms of 18 the responsibilities. 19 Q. Understood, and we'll talk through that. 20 Generally speaking, were you asked to render opinions 21 about the conduct of the finished dose manufacturers 22 in preparing your report in this case? 23 A. I was asked to address the API and 24 finished dose manufacturers as it relates to my area. 25 So that's different than the expansive to all areas,</p>

<p style="text-align: right;">Page 286</p> <p>1 so for example, it's my understanding that other 2 experts are going to handle some of the issues 3 related to Teva and Torrent with regulatory -- some 4 other regulatory compliance issues. But I have 5 considered them as their role the people who were 6 buying and using the API from ZHP.</p> <p>7 Q. And what I'm going to attempt to clarify 8 is whether your references to the finished dose 9 manufacturers, and specifically Teva, are intended to 10 either be factual information that's important for 11 your report, or in its contents, talking generally 12 about obligations that would apply to any finished 13 dose manufacture, or if they are criticisms about the 14 specifics about the finished dose manufacturers in 15 this case. And I'll get more specific, but that's 16 generally what I'm trying to figure out, okay?</p> <p>17 A. Sure.</p> <p>18 Q. You mentioned that there are other 19 experts who have worked on different areas. You've 20 talked about chemistry and CGMPs. Are you aware that 21 there are other experts who are directly addressing 22 the conduct of the finished dose manufacturers?</p> <p>23 A. Yes, I believe so. And I'm also aware 24 of, I believe I've read at least one report from one 25 of Teva's experts that's on my list, that was in the</p>	<p style="text-align: right;">Page 288</p> <p>1 screen-share it for you if that would be more 2 convenient. You just let me know.</p> <p>3 A. On that one I've seen it before, so if 4 you want to just screen-share it, that's fine.</p> <p>5 VIDEOGRAPHER: We're at six hours, 16 6 minutes.</p> <p>7 MR. HARKINS: Thank you. And thanks for 8 the option on the exhibit, Steve.</p> <p>9 Q. Doctor, let me know when you can 10 hopefully see the document, I'll go up to the top 11 just to confirm, is this the Plaintiff's objections 12 and responses to the notice of videotaped deposition 13 for you?</p> <p>14 A. Yes, that's correct. And I -- I went 15 over this and assisted in terms of responding to the 16 notice of deposition, and I saw this document after 17 it was filed.</p> <p>18 Q. All right, and specifically I'm going to 19 go down, I'm interested in just confirming the part 20 that you brought up where you mentioned that you have 21 reviewed a number of additional expert reports 22 including the ones at the end of this paragraph, at 23 the top of page 11 for defense expert reports of 24 Dr. Steven Baertschi, Dr. Roger Lea Williams, and 25 Mr. Timothy Anderson, do you see that?</p>
<p style="text-align: right;">Page 287</p> <p>1 list that Mr. Vaughn sent around, hopefully you 2 received that, in response to the notice of 3 deposition.</p> <p>4 MR. HARKINS: And I'll go ahead, I don't 5 believe the objection responses of the notice have 6 been marked as an exhibit, and if that's the case I'm 7 going to go ahead and mark this and I believe this is 8 now Exhibit 11, is that right?</p> <p>9 MR. VAUGHN: I think you're right, 10 Steve.</p> <p>11 EXH (Plunkett Exhibit 11, Plaintiffs' 12 Objections and Responses to Defendants' Notice of 13 Deposition of Laura Plunkett, marked for 14 identification, as of this date.)</p> <p>15 MR. HARKINS: We'll introduce that. And 16 because you mentioned it, are we using a prefix to 17 that or do I just add it?</p> <p>18 MR. VAUGHN: Can we get a time check as 19 we're getting the exhibit up and loaded?</p> <p>20 VIDEOGRAPHER: Sure, stand by for that.</p> <p>21 MR. VAUGHN: Thank you. 22 (A pause in the proceedings.)</p> <p>23 Q. All right, Dr. Plunkett, the exhibit has 24 been introduced with your objections and responses 25 and if you would like to pull that up there or I can</p>	<p style="text-align: right;">Page 289</p> <p>1 A. Yes.</p> <p>2 Q. And those are Teva experts, do you 3 recall seeing in those reports?</p> <p>4 A. Yes, and Dr. Baertschi is one I 5 certainly recall was, and I believe Dr. Williams as 6 well. Dr. -- Mr. Anderson, I don't recall his in any 7 detail, but -- the ones I remember are ones that may 8 have actually mentioned my name, so I spent more time 9 with those.</p> <p>10 Q. Are there any other Teva depositions, 11 reports, or corporate documents that you reviewed in 12 between the time that you completed your report and 13 the deposition today?</p> <p>14 A. No. I don't believe so.</p> <p>15 MR. HARKINS: I'll go ahead and stop 16 sharing that.</p> <p>17 Q. I'd like to go and just talk 18 specifically about the times that you do discuss Teva 19 in your report, and then some other times where 20 you're referring to finished dose manufacturers more 21 generally. Before I go to that, do you feel that you 22 have reviewed sufficient material to form opinions 23 about every aspect of the Teva Defendants' conduct in 24 this case?</p> <p>25 MR. VAUGHN: Object to form.</p>

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<p style="text-align: right;">Page 290</p> <p>1 A. I don't know what you mean by every 2 aspect, but I would -- so what I would say to you is 3 I believe I have reviewed sufficient information to 4 form the opinions I have that apply to finished dose 5 manufacturers including Teva, as I -- as I have put 6 them forth. And again, there are other experts I 7 know that are going into much more detail on some of 8 the other -- the issues that I don't cover. So that 9 may be issue -- you know, may be issues for Teva. 10 Q. And if there are other experts who are 11 covering this in more detail for Plaintiffs, you 12 would defer to their opinions on those subjects? 13 A. Well, I just don't go there. That's 14 beyond my opinions, beyond the scope. As far as 15 whether I defer to anybody else, I don't typically 16 defer to somebody, I just say that's something that 17 I'm not doing, unless I mention them specifically in 18 my report and say that, you know, I concur -- like 19 Dr. Hecht, I felt that his report and his, discussion 20 based on my understanding of the chemistry and his 21 discussion of the literature, was such that I wanted 22 to describe it. 23 Q. Okay. Well, I'd like just to quickly 24 walk through and make sure that I understand where 25 you have referred to Teva. Do you have a copy of</p>	<p style="text-align: right;">Page 292</p> <p>1 Q. Doctor, turning to paragraph 45 of your 2 report, which I believe is the next referenced 3 directly to Teva -- 4 A. I'm there, yes. 5 Q. -- and there are two sentences at the 6 end. One says, "It should be noted that all ANDA 7 holders have a responsibility to either perform such 8 risk assessments or to ensure that such risk 9 assessments have been performed in any API they may 10 incorporate into their finished drug products," do 11 you see that? 12 A. Yes. 13 Q. And the question I have about that is, 14 is that a statement by you generally that ANDA 15 holders have a responsibility to insure certain 16 things about the API they have incorporated in their 17 finished dose drug products, or is that intended as a 18 criticism of Teva's steps taken to perform risk 19 assessments to insure the quality of their API? 20 MR. VAUGHN: Object to form. 21 A. To -- this is as written, a general 22 section of the report, which is here as a general 23 statement about ANDA holders which would apply at 24 Teva, because they are finished dose manufacturers. 25 But if I meant, if I was referring to a specific</p>
<p style="text-align: right;">Page 291</p> <p>1 your report with you? 2 A. I do, yeah, if you want to tell me where 3 you want to go. 4 Q. Sure, and I think most of these should 5 be pretty straightforward. If you can go ahead and 6 look on page 35, there is a footnote. 7 A. Um-hum, yes. 8 Q. And that reference to Teva, that's just 9 factual information as to their status in the case as 10 a Defendant, right? 11 A. Yes, and I would say also, on page 4, 12 where a footnote, "Valsartan containing products," I 13 understand Teva makes some of those products, even 14 though I don't necessarily link one specifically to 15 Teva. 16 MR. VAUGHN: Steve, are you on this 17 screen-share for video purposes or are you okay with 18 it not being on video? 19 MR. HARKINS: I think it's fine if we're 20 not on video. 21 Q. But, Doctor, if you could use fuller -- 22 MR. HARKINS: -- or if anybody else 23 needs to see it, let me know. But we're just going 24 to walk through some sections of her report quickly. 25 MR. VAUGHN: Understood.</p>	<p style="text-align: right;">Page 293</p> <p>1 document related to Teva or Torrent, I would cite it 2 and I have not. 3 In the next sentence I say, "This duty 4 would assure the purity applies to them." So I am 5 saying that they had a duty to ensure purity. And so 6 my criticism obviously would be that they sold 7 product that contained the impurity 'cause those 8 products were recalled as well. 9 So as a result of that, that would fall 10 as a failure to insure the purity before the products 11 were distributed. 12 Q. And do you feel that you've reviewed 13 sufficient documents and material to comment and 14 provide opinions on the risk assessments performed by 15 Teva related to the ZHP API? 16 MR. VAUGHN: Object to form. 17 A. So I have not done a lot of -- I have 18 done as much investigation as the other experts that 19 are dealing with some of these GMP issues have done 20 into the Teva and Torrent files. 21 What I will tell you is, the evidence I 22 have seen is that I don't see Teva and Torrent in the 23 documents, because I actually asked for some of these 24 documents, that I haven't seen the evidence, and I 25 haven't seen it discussed in the ZHP documents,</p>

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<p style="text-align: right;">Page 294</p> <p>1 either, whether they are the kind of conversations or 2 questions from Teva and Torrent that you saw from 3 either Novartis, when they discovered the problem in 4 2018, when they were looking at qualifying of ZHP for 5 use as an API for finished dose products, or for 6 things that were gone over this morning by -- that I 7 had not reviewed before, by -- gosh, Ms. Miller, 8 Jessica, about the interactions that other companies 9 were having in terms of going back and forth with 10 ZHP. So I haven't seen that evidence. If it exists, 11 you're going to show it to me, I can consider it, but 12 I have not seen that. 13 Q. Well, Doctor, I'm not interested in 14 things that you didn't review. I'm asking if you 15 feel like, in rendering your opinions, you have 16 reviewed sufficient information, not just to make the 17 general statement that there was a duty for these 18 finished dose manufacturers to perform risk 19 assessments, but have you reviewed sufficient 20 documents to come in and offer opinions in your 21 report and then eventually at trial about whether the 22 finished dose manufacturers, including Teva, 23 adequately performed their risk assessments, have you 24 reviewed those risk assessments? 25 MR. VAUGHN: Object to form. Asked and</p>	<p style="text-align: right;">Page 296</p> <p>1 think those are the main areas that I covered that 2 would be Teva and Torrent specific. 3 Did that help you? I'm just trying to 4 summarize it to get it going, but -- 5 Q. Sure. Let me go ahead and point you, 6 and I'm happy to screen-share if we'd like here, to 7 the appendix that you list the materials that you did 8 consider prior to providing your report in this case. 9 A. I have it. I have my appendix C, so you 10 want to just tell me which page? 11 Q. Okay. The first page of the appendix, 12 it's following 47 but unnumbered, listing number of 13 depositions here. Do you see that? 14 A. Yes. 15 Q. Now, I'll represent to you that none of 16 these are depositions of Teva corporate employees. 17 If you disagree with that, let me know and I'm happy 18 to explain the identity of any of these individuals. 19 Do you think that you reviewed any Teva 20 depositions? 21 A. I reviewed depositions where Teva was 22 in, was at the deposition and may have been even 23 asked for questions; but no, in these depositions, 24 you're correct. These were employees of ZHP and Teva 25 relied on ZHP to produce their API.</p>
<p style="text-align: right;">Page 295</p> <p>1 answered. 2 A. I have -- the documents that I have seen 3 at this point in time, I feel comfortable allow me to 4 say what I say in my report. So if you're asking me 5 for, is there an opinion that is not expressed in my 6 report, or when I use the word "ANDA holders," if I'm 7 using the general word "ANDA holders," however I'm 8 stating that opinion, that would encompass Teva and 9 Torrent. But my language is very carefully chosen 10 based upon the information and evidence that I have 11 reviewed. 12 So you were correct in stating that this 13 first sentence you've read was a general statement 14 about what the responsibilities of ANDA holders are. 15 The second sentence that you didn't read 16 in, where I say in this case, I'm letting you know 17 that it's my opinion that that duty goes to them, 18 too, Teva and Torrent, because those -- and Prinston 19 and ZHP because four of those actually made a 20 finished dose, so it's not just a ZHP opinion. 21 And then earlier today I made some 22 statements to you that I think if you get to it, back 23 of the back, I do have some specific opinions about 24 adulteration, and as the finished dose being 25 adulterated if it contained an adulterated API. I</p>	<p style="text-align: right;">Page 297</p> <p>1 Q. But my question is, you did not review 2 any depositions of any Teva corporate witness, 3 correct? 4 A. That is correct. If it's not listed 5 here, this is all I have reviewed in terms of 6 corporate witnesses. 7 Q. And you identified thee reports that 8 were provided last month that you've also not 9 reviewed the depositions of any Teva expert witnesses 10 that have already taken place, correct? 11 A. I didn't know that any expert witness 12 depositions had taken place. Usually the defense 13 experts don't go until after the Plaintiffs's 14 exhibits go; but if I'm mistaken, I have not. I 15 would actually expect to potentially review that 16 information. 17 Q. Turning to the next page, there is a 18 section that begins to list the Teva corporate 19 documents that you reviewed. Do you see that, 20 towards the bottom in the right-hand column? 21 A. Yes. 22 Q. There are a number of documents here 23 that have "(ECTD)" in parentheses after the 24 description, do you see those? 25 A. Yes.</p>

<p style="text-align: right;">Page 298</p> <p>1 Q. Those are the ANDA files in ECTD format, 2 is that correct? 3 A. That's correct. 4 Q. Then there are a handful, one, two, 5 three, four, five, six, seven, eight additional Teva 6 documents on the next page. 7 A. Yes, that's correct. And it's also some 8 non-ECT documents on the bottom of the second page as 9 well. 10 Q. Correct. These are all the Teva 11 documents that you reviewed in preparing to render 12 your report in this case, correct? 13 A. These are all the documents with the 14 Teva Bates but I assume that means, in my experience, 15 they came from Teva's files, that is true. But there 16 are a number of documents in the ZHP discovery that 17 are discussing or may be or would be relevant to 18 Teva. But you're correct, as far as what was in 19 Teva's discovery, these are the only ones that I 20 have. 21 Q. So for example, in connection with the 22 opinion that you, I believe, have said you intend to 23 offer about the risk assessments performed by Teva 24 and their evaluation of their supplier, you did not 25 review the risk assessment that they performed on ZHP</p>	<p style="text-align: right;">Page 300</p> <p>1 wasn't given anything. 2 Q. You didn't feel that Teva's risk 3 assessment evaluating and obtaining information about 4 their supplier's process control change was relevant 5 to whether Teva appropriately evaluated their 6 supplier's process control change? 7 MR. VAUGHN: Object to form. 8 A. Given that ZH -- no, I think my opinion 9 is, given that ZHP's risk assessment was ineffective, 10 and in the DMF, which is what Teva and Torrent don't 11 have access to, right, and then not seeing an 12 agreement between Teva and Torrent, and I did look 13 for this, whether or not there was a -- I asked this 14 question, was there a confidentiality or a 15 non-disclosure agreement where Teva and Torrent asked 16 to review the DMF, and it's my understanding that was 17 not the case. So those are the kinds of questions I 18 asked. 19 So the issue is, if you never reviewed 20 the details of their DMF, then obviously, you can't 21 correct any deficiencies as an ANDA manufacturer that 22 existed. The deficiency started with ZHP but by not 23 having access to those details, and instead relying 24 on representations made by ZHP, where we know that 25 some of those representations were not adequate in</p>
<p style="text-align: right;">Page 299</p> <p>1 and ZHP's process in connection with the process 2 change, did you? 3 MR. VAUGHN: Objection, form, lack of 4 foundation. 5 A. If it's not one of these documents, no, 6 I would have not have reviewed it. So you have to 7 tell me, because I don't recall what each of these 8 documents was -- 9 Q. I'll certainly represent to you it is 10 not one of these documents. You did not review that 11 document in preparing to render your own opinion, 12 correct? 13 MR. VAUGHN: Object to form. 14 A. I did not, but don't forget the issue 15 that you have here, and maybe this is something I 16 talked about this morning, is that as an ANDA holder, 17 Teva has a responsibility to ensure that their 18 supplier has done all the right things. And given 19 that the supplier didn't do the right things, I 20 haven't seen a document to indicate that Teva 21 questioned them about that. And I did ask about that 22 from the attorneys, and I don't have any documents 23 that I have reviewed at this point in time. 24 Some of these requests and things came 25 right before my report was filed. But I didn't --</p>	<p style="text-align: right;">Page 301</p> <p>1 terms of the work they did, it falls to -- 2 Q. Doctor, during this session, I'm never 3 asking you about the conduct of ZHP and I'm never 4 going to be asking for a response that details the 5 conduct of ZHP. And we have very limited time for 6 the two remaining Defendants, and I am strictly 7 focused on your opinions about Teva's conduct and, by 8 extension, whether you evaluated that conduct for the 9 finished dose manufacturers, okay? 10 A. Yeah, and that's why I mentioned the 11 ANDA, the nondisclosure because -- 12 Q. You -- 13 A. -- go ahead -- I'm very familiar with 14 NDAs in licensing agreements, when I do due diligence 15 and people are looking at files to understand what's 16 going on. And that's -- that's the reason, so that 17 may be a separate opinion that isn't what you're 18 asking. And I apologize, but I did -- 19 Q. I am certainly not asking about that 20 opinion. I'm just asking about your opinion about 21 Teva's risk assessment and evaluation of their 22 supplier, not to do with ZHP documents. And I just 23 want to confirm, you did not review any of the Teva 24 risk assessments of their supplier, ZHP, correct? 25 MR. VAUGHN: Object to form.</p>

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<p style="text-align: right;">Page 302</p> <p>1 A. If it's not one of ones listed, I did 2 not, that is true. And we started there, and you 3 represented and I'll take your representation. 4 Q. I will represent to you that there was a 5 change control instance report that documented a 6 whole series of steps that Teva took in connection 7 with evaluating the change to the process that 8 eventually generated the impurity. This is not on 9 your list of materials considered, that is also not 10 something that you considered in rendering your 11 opinions about Teva's conduct in evaluating their 12 supplier, correct? 13 MR. VAUGHN: Object to form, lack of 14 foundation. You may answer. 15 A. If it's not in my list, I didn't review 16 although I would argue that that area is one that I 17 understand is being covered by other experts in terms 18 of looking at the change control documents and those 19 documents which have to do with GMP compliance, 20 obviously, for the finished dose manufacturer. 21 Because they have separate responsibilities from -- 22 as well. 23 Q. And you're familiar with the closed 24 portion of the DMF that is not available and visible 25 to the finished dose manufacturer in the course of</p>	<p style="text-align: right;">Page 304</p> <p>1 can make their own arrangements. So it isn't that 2 they couldn't do that, it's just that I don't think 3 it was done based on the evidence I have. 4 Q. Doctor, are you aware of any indication 5 or evidence that you can point to, and I'm talking 6 specifically about Teva here, are you aware of any 7 piece of information or document that, according to 8 your opinion, should have led Teva to seek access to 9 the closed portion of ZHP's DMF? 10 MR. VAUGHN: Object to form. 11 A. I would say that the information that 12 I'm aware of would be the fact that they were 13 referring to the Drug Master Files in their ANDA from 14 ZHP; so in other words, they were referring to the 15 Drug Master File. It's my. 16 Understanding they didn't have access to 17 it. It would be my advice to take a look so you have 18 an understanding, particularly when the DMF you're 19 referring to was not the one that is -- is not the 20 process that related to Diovan, which was the 21 Reference Listed Drug. 22 Q. You've not seen any document or evidence 23 whatsoever that Teva was aware of the presence of 24 NDMA or NDEA in Valsartan prior to June 2018, have 25 you?</p>
<p style="text-align: right;">Page 303</p> <p>1 getting an ANDA approved, etc., right? 2 MR. VAUGHN: Object to form. 3 A. I am aware that Drug Master Files are 4 typically closed unless companies come to an 5 agreement to share information. That's why I 6 mentioned getting -- I don't know what you call it, a 7 confidentiality agreement, a nondisclosure agreement 8 of information, and that's why I asked, did those 9 exist, and I was told that there was no indication 10 they did in the discovery documents. 11 Q. Is your criticism of Teva that they 12 failed to seek access to the closed portion of ZHP's 13 DMF? 14 MR. VAUGHN: Object to form. 15 A. Yes, given that -- give the situation 16 that existed here, that's exactly right. I mean, 17 again, this is advice I've given to clients before, 18 when they are talking about having responsibility for 19 something else, that another company does that, it's 20 not within their purview. In fact, if you look at -- 21 I know you have limited time, sorry, but in a -- I 22 cite to a document in my reliance materials that is a 23 presentation put on by the FDA about Drug Master 24 Files, and it makes it very clear that you're right, 25 they are closed. But it also indicates the companies</p>	<p style="text-align: right;">Page 305</p> <p>1 MR. VAUGHN: Object to form. 2 Q. Teva specifically. 3 A. I don't believe so, no. 4 Q. There was a statement during the course 5 of your deposition earlier today where you said Teva 6 and Torrent also have duties to evaluate their API 7 suppliers and insure they produce a quality product. 8 Is that effectively a restatement of the opinion that 9 we've been talking about here? 10 MR. VAUGHN: Object to form. 11 A. Yes, well -- it's a different way of 12 saying what we already read into the record, that's 13 exactly right. And the reason I stated it this 14 morning was, I wanted to make sure that, since you 15 were going to ask questions, that you knew I 16 wasn't -- if you haven't seen that part of my report, 17 which I assume you had, that I do put a 18 responsibility here in terms of that relationship, 19 that Teva and Torrent have a responsibility for the 20 API as well, because they are a finished dose 21 manufacturer using that. 22 Q. Turning to paragraph 52 of your 23 report -- 24 A. Yes. 25 Q. -- I believe here you're referring to</p>

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<p style="text-align: right;">Page 306</p> <p>1 ANDA holders in the second full sentence where it 2 says, "Yet neither ZHP or any of the other ANDA 3 holders performed the necessary risk assessment for 4 degradation products from ZHP's Valsartan processes. 5 Such risk assessments, if adequately performed, 6 should have led to identification of the potential 7 and actual presence of nitrosamine impurities in 8 ZHP's Valsartan product," you see that there, right? 9 A. I do. 10 Q. This situation where you are referring 11 to ANDA holders including Teva and stating an opinion 12 that they should have performed necessary risk 13 assessments for degradation products that -- is that 14 your opinion here? 15 MR. VAUGHN: Object to form. 16 A. My opinion is, as I stated, and if 17 you're an ANDA holder that was using ZHP's process 18 and product, yes, I would refer to Teva and Torrent. 19 Q. As we have already established, you did 20 not review the risk assessment that Teva performed in 21 connection with ZHP's process in forming this 22 opinion, correct? 23 MR. VAUGHN: Asked and answered. 24 A. That's correct. The document that 25 you're referring to that I haven't seen, yes, I have</p>	<p style="text-align: right;">Page 308</p> <p>1 case, as we know, the ZHP API contained impurities of 2 NDMA and NDEA that are tied to the changes in the 3 process. And based upon, as we talked a lot this 4 morning, based upon what was -- should have been 5 known -- could have been known based on the chemical 6 literature, and then of course looking what Dr. Hecht 7 had said about the foreseeability, that lack of a 8 full assessment in my view was very important to why 9 we got to where we were, which was adulterated 10 products. 11 But you're correct, I am not seeing the 12 document that you're referring to. I've seen much 13 more information related to ZHP than I have you -- 14 have Teva -- I don't mean you personally, I 15 apologize, than I have for Teva. 16 Q. And the fact that you've not evaluated 17 Teva's own, not ZHP's, Teva's own risk assessment, or 18 their change control, or the policies that they have 19 put in place around this change, doesn't, you feel, 20 impact your ability to provide an opinion on Teva's 21 conduct related to the risk assessment? 22 MR. VAUGHN: Object to form. Lack of 23 foundation. 24 A. I don't believe it does, based on the 25 opinion that I'm providing. But you'll notice that</p>
<p style="text-align: right;">Page 307</p> <p>1 not -- referring to the change control, what you call 2 the change control document, is that what you called 3 it? 4 Q. That's another document that you didn't 5 review. The actual risk assessment for the ZHP 6 process which you did not review, you didn't feel 7 that it was important to review that document in 8 coming to your opinion that Teva's risk assessment 9 related to this product was insufficient? 10 MR. VAUGHN: Object to form. 11 A. Well, there certainly would be other 12 documents I would consider, but I don't think it 13 would change my opinion based on the facts in this 14 case, which is that I did ask was there some type of 15 a sharing of confidential documents, such as that you 16 could do -- in order to -- in order for you as Teva 17 or -- not you, but in order for Teva as a company or 18 Torrent as a company in my opinion to be able to do a 19 proper risk assessment, they would need to see the 20 details in the DMF. 21 It's my understanding they did not ask 22 for that access so, as a result of that, they are in 23 a position in relying on the adequacy of risk 24 assessment from ZHP. 25 Obviously, based on the facts in this</p>	<p style="text-align: right;">Page 309</p> <p>1 I'm only going so far. And as a result, there are 2 other experts that were handling much more detailed 3 reviews and statements about the compliance with GMP 4 or lack of compliance for all of the different 5 parties involved. 6 Q. I'd like to turn to paragraph 54 of your 7 report. 8 A. I'm there, yes. 9 Q. In the second paragraph below where you 10 have quoted? 11 A. Starting with "For the materials," or 12 starting with "Regarding," or starting with "The 13 Valsartan"? 14 Q. Below, starting with, "The Valsartan." 15 A. Yes, I'm there. 16 Q. The last sentence that starts on that 17 page indicates, "None of the Valsartan ANDAs or 18 supplements disclosed NDMA or NDEA as an impurity." 19 Correct? 20 A. Oh, yeah, you skipped down, I see where 21 you are. Yes. Yes, that's my statement. You've 22 read that. You didn't read the whole sentence 23 before, but you read the sentence at the end, I see 24 that, yes. 25 Q. Do you agree, I believe we've already</p>

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<p style="text-align: right;">Page 310</p> <p>1 discussed that you've not identified anything to</p> <p>2 indicate that Teva was aware of the presence of NDMA</p> <p>3 or NDEA in Valsartan prior to June 2018, correct?</p> <p>4 A. Based on the documents I've seen, that's</p> <p>5 my understanding, that they had not gained that</p> <p>6 knowledge until then, that's correct. But they still</p> <p>7 have responsibilities which I've tried to lay out in</p> <p>8 my report.</p> <p>9 Q. And, Doctor, I'm being very specific to</p> <p>10 the actual information that was contained in the ANDA</p> <p>11 because your final statement in this paragraph is,</p> <p>12 "The Valsartan finished doses that contained NDMA or</p> <p>13 NDEA did not comply with the specifications with the</p> <p>14 ANDAs." I believe that's "within the ANDAs," is that</p> <p>15 right?</p> <p>16 A. Right, because it doesn't mention the</p> <p>17 presence of the genotoxic impurity.</p> <p>18 Q. It's your opinion that the product which</p> <p>19 met all then-existing specifications for the</p> <p>20 Valsartan product contained in the ANDA, nonetheless</p> <p>21 violated those specifications?</p> <p>22 MR. VAUGHN: Objection, form, misstates</p> <p>23 facts in evidence.</p> <p>24 A. If the finished dose contained, as I</p> <p>25 say, Valsartan finished doses that contained NDMA or</p>	<p style="text-align: right;">Page 312</p> <p>1 adulteration opinion. I understand that you would</p> <p>2 like to talk about that. I'm asking about whether</p> <p>3 it's your opinion that it violates the specifications</p> <p>4 in the then-existing ANDAs. Have you reviewed the</p> <p>5 report of Plaintiffs' other expert, Philip Russ?</p> <p>6 MR. VAUGHN: Objection to form.</p> <p>7 A. Dr. Russ, yes, I've review his report,</p> <p>8 yes.</p> <p>9 Q. Did you review his deposition that he</p> <p>10 last week, his transcript?</p> <p>11 A. No, I wouldn't have had time to review</p> <p>12 that last week, but I did not. That's the one that</p> <p>13 you're saying has been available? No, I haven't seen</p> <p>14 that.</p> <p>15 Q. Is it your understanding that Dr. Russ</p> <p>16 is opining on the conduct of the Teva Defendants, the</p> <p>17 Torrent Defendants, the specifically the finished</p> <p>18 does manufacturers in this case?</p> <p>19 A. That he has opinions about that? Yes.</p> <p>20 Q. Are you aware that Dr. Russ said he</p> <p>21 would stipulate that the specifications for the</p> <p>22 then-existing ANDAs were not violated on the record</p> <p>23 during his deposition?</p> <p>24 MR. VAUGHN: Object to form, lack of</p> <p>25 foundation.</p>
<p style="text-align: right;">Page 311</p> <p>1 NDEA did not comply with the specifications of the</p> <p>2 the ANDAs, on this part of that description of the</p> <p>3 specification for the ANDAs is described by, in a</p> <p>4 text above, where there was a -- a -- what were you</p> <p>5 go to call -- a warranty given by ZHP that there was</p> <p>6 no genotoxic potential, and also, as a result, the</p> <p>7 specifications don't list as potential genotoxins,</p> <p>8 even though we know that the -- from the -- the</p> <p>9 evidence in the case that developed that indeed those</p> <p>10 processes had the potential to produce NDEA and NDMA;</p> <p>11 so all I'm trying to say is, it ties in later with</p> <p>12 this issue of, would the products indeed be deemed</p> <p>13 adulterated.</p> <p>14 And my point is, regardless of whether</p> <p>15 you're an ANDA holder or you're the API manufacturer,</p> <p>16 if the finished dose of Valsartan had these genotoxic</p> <p>17 impurities in them, they would be deemed adulterated,</p> <p>18 because you can't separate the two.</p> <p>19 You can't -- the API is proposing to the</p> <p>20 finished dose form, unless Teva or Torrent did</p> <p>21 further purification, which I've seen no evidence</p> <p>22 that they did, as described in the expert reports of</p> <p>23 others as well, and no description in the defense</p> <p>24 expert reports that they did that --</p> <p>25 Q. Doctor, I'm not asking about your</p>	<p style="text-align: right;">Page 313</p> <p>1 A. I'm not aware of anything specific he</p> <p>2 said because I haven't read his deposition. So all I</p> <p>3 can say is, I would be happy to review his deposition</p> <p>4 at some point in time, but I have not had a chance to</p> <p>5 do so. I have seen his report, and I don't recall</p> <p>6 that language in his report.</p> <p>7 MR. HARKINS: I'm going to go and</p> <p>8 introduce the deposition of Plaintiff's expert Philip</p> <p>9 Russ as the next exhibit.</p> <p>10 EXH (Plunkett Exhibit 12, transcript of</p> <p>11 deposition of Phillip Russ, marked for</p> <p>12 identification, as of this date.)</p> <p>13 MR. VAUGHN: Can I get another time</p> <p>14 check while we're getting the exhibit up?</p> <p>15 VIDEOGRAPHER: Certainly, stand by.</p> <p>16 (A pause in the proceedings.)</p> <p>17 Q. And Dr. Plunkett, to move this along,</p> <p>18 I'm going to go ahead and screen-share.</p> <p>19 VIDEOGRAPHER: We're at six hours and 49</p> <p>20 minutes.</p> <p>21 MR. VAUGHN: Dr. Plunkett, go ahead and</p> <p>22 download it still so you can see it in context, if</p> <p>23 you want to see the pages before and after.</p> <p>24 Q. Let me know when you're able to see the</p> <p>25 Exhibit Share.</p>

<p style="text-align: right;">Page 314</p> <p>1 A. I can see it, yes.</p> <p>2 Q. Starting at the top, the question, "Are</p> <p>3 you aware that, even at the highest levels of</p> <p>4 impurities reported in ZHP API anywhere in world the</p> <p>5 testing showed, according these standards in the</p> <p>6 compendial specifications, that the impurities were</p> <p>7 below the reporting thresholds, correct?"</p> <p>8 There's an objection. Do you see that</p> <p>9 question?</p> <p>10 A. Yes, I do.</p> <p>11 Q. And his response, "I'll stipulate to</p> <p>12 that, yes. I mean, my concern again isn't about the</p> <p>13 meeting of specifications."</p> <p>14 Do you see that?</p> <p>15 A. I do.</p> <p>16 MR. VAUGHN: Object to form, incomplete</p> <p>17 document.</p> <p>18 A. I do see that, but going back up to the</p> <p>19 question that's being asked there, I don't know. I</p> <p>20 haven't read this entire depo and I haven't talked to</p> <p>21 Dr. Russ. But when you're using the words,</p> <p>22 "below" -- "The impurities below reporting</p> <p>23 thresholds," when you're pointing to the .1 percent</p> <p>24 and that's how he is -- he is reading that, that's a</p> <p>25 different question than, and a different opinion than</p>	<p style="text-align: right;">Page 316</p> <p>1 Q. -- very last sentence says, "Quality</p> <p>2 agreements do not absolve finished dose manufacturers</p> <p>3 from their responsibilities regarding drug quality."</p> <p>4 Did I read that correctly?</p> <p>5 A. I'm looking for where you are. The</p> <p>6 first sentence doesn't say that.</p> <p>7 Q. Very last sentence in paragraph 55.</p> <p>8 A. Oh, I'm sorry. Got to go to the next</p> <p>9 page, okay. Apologize.</p> <p>10 Yes, I agree that's what it stated.</p> <p>11 Q. Is this a general statement or did you</p> <p>12 evaluate and have an opinion as to the adequacy of</p> <p>13 the quality agreements in place for the finished dose</p> <p>14 manufacturers in this case?</p> <p>15 A. It's first a general statement, although</p> <p>16 I did look at the quality agreements I cited, which</p> <p>17 some of those, I believe at least one of those,</p> <p>18 several of those are Teva documents. So -- and the</p> <p>19 top of paragraph 55, I'm referring to those documents</p> <p>20 and my review of those documents.</p> <p>21 Q. And I understand you reviewed them. I</p> <p>22 guess my question is, do you have an opinion that is</p> <p>23 critical of the quality agreements in place for the</p> <p>24 finished dose manufacturers that you intend to offer</p> <p>25 in this case?</p>
<p style="text-align: right;">Page 315</p> <p>1 what I'm expressing.</p> <p>2 I'm expressing the opinion that when the</p> <p>3 finished dose product contains NDMA or NDEA, it does</p> <p>4 not comply with specifications in the ANDAs which are</p> <p>5 not to contain levels of potent genotoxins at any</p> <p>6 level, up to even above or below .1 percent. That's</p> <p>7 not part of the specification that it's okay for</p> <p>8 there to be a genotoxin at a level less than .1</p> <p>9 percent.</p> <p>10 I don't argue with you that part of the</p> <p>11 issues here relate to the inadequate work that ZHP</p> <p>12 may have done. But again, as a finished dose</p> <p>13 manufacturer, referring to their Drug Master File,</p> <p>14 and relying on them for their work, there is</p> <p>15 responsibility that comes with that. And so to me,</p> <p>16 the lack -- when I make the point that they don't</p> <p>17 comply, it has to do with just that issue.</p> <p>18 So I don't know that Dr. Russ and I are</p> <p>19 totally in disagreement here, but I'd have to read</p> <p>20 his deposition to know more about that.</p> <p>21 MR. VAUGHN: Is that Exhibit 12, Steve?</p> <p>22 MR. HARKINS: Yes.</p> <p>23 Q. Doctor, turning to paragraph 55 of your</p> <p>24 report --</p> <p>25 A. Yes?</p>	<p style="text-align: right;">Page 317</p> <p>1 MR. VAUGHN: Object to form.</p> <p>2 A. Are you asking -- let me ask a</p> <p>3 clarifying question. Are you asking me, do I have a</p> <p>4 criticism of specific language or specific</p> <p>5 responsibilities that were shared with ZHP, why they</p> <p>6 did that? No. What I'm saying to you is, however,</p> <p>7 that --</p> <p>8 Q. Are --</p> <p>9 A. -- what I'm saying is, because you have</p> <p>10 a quality agreement, that doesn't mean you can run</p> <p>11 away from your responsibility to ensure that your</p> <p>12 product is safe for use, doesn't put patients at</p> <p>13 risk, and indeed is not adulterated.</p> <p>14 Q. Understood. You've already answered the</p> <p>15 question. We can move on to paragraph 57.</p> <p>16 Here, in the third sentence you state,</p> <p>17 "In this case, there is no evidence to show that any</p> <p>18 of the ANDA holders took actions on their own to warn</p> <p>19 physicians and their patients about the presence of</p> <p>20 impurities in Valsartan drug products that were</p> <p>21 carcinogens." Are you there?</p> <p>22 A. Yes.</p> <p>23 Q. I'm right in interpreting that as a</p> <p>24 criticism of the actions taken by the finished dose</p> <p>25 manufacturers, including Teva?</p>

<p style="text-align: right;">Page 318</p> <p>1 A. Yes. Earlier in my report, I referred 2 to, there's the ability for manufacturers to do -- to 3 do healthcare provider letters or direct 4 communication, and I did not see that having been 5 done. 6 Q. I understand that you didn't see it. 7 You didn't review in forming this opinion any of the 8 recall notices which were sent by Teva, did you? 9 MR. VAUGHN: Objection to form. 10 A. Nor am I aware that such existed. I am 11 aware of recall notices existing, yes, but this is a 12 different issue. 13 Q. Did you review any of the patient-level 14 recall notices that Teva sent in connection with the 15 recall? You didn't review any of those, did you? 16 MR. VAUGHN: Objection. 17 A. If they are not in my reliance material, 18 obviously I have not. So you can represent for me 19 that they are there or they are not there. 20 Q. Did you review any of the information 21 surrounding Teva placing a hold on all products 22 containing ZHP API as of June 21st, 2018, in forming 23 this opinion? 24 MR. VAUGHN: Object to form. 25 A. If it was at the FDA website, I -- I may</p>	<p style="text-align: right;">Page 320</p> <p>1 So I'm talking about specific information about the 2 risks associated with exposure to NDMA and NDEA. 3 Q. This is not directed at the conduct of 4 the finish dose manufacturers here. 5 MR. VAUGHN: Object to form. 6 A. I'm referring -- I'm referring to 7 communication that they could have done directly 8 related to the safety concerns raised that I did not 9 see in their healthcare provider letters, for 10 example. 11 I'm not disputing that you sent recall 12 notices. You're required to do that, especially 13 since you were doing patient-level recall. 14 MR. HARKINS: Those are all the 15 questions I have for you, Doctor. I believe that 16 there may be counsel for Torrent who would like to 17 follow up as well. 18 MR. VAUGHN: Can we get another time 19 check then, because I think we're down to four 20 minutes. 21 VIDEOGRAPHER: Three minutes left. 22 MS. NAGLE: I'm going just go ask that 23 we take a five-minute break. 24 THE WITNESS: That's fine with me, is 25 that fine with you --</p>
<p style="text-align: right;">Page 319</p> <p>1 have seen things that were specific to them. But if 2 it's not a publicly-available document of the FDA 3 website and it's not listed in my reliance list C, 4 no. And I don't remember ever that I saw at the FDA 5 website. There's a lot there. And there is 6 information in the -- there's a database where you 7 can look at recalled products. 8 Q. In forming this opinion that the ANDA 9 holders, including Teva, didn't take action to warn 10 physicians and their patients, you did not review any 11 of the documents demonstrating information that Teva 12 communicated to physicians and patients and steps 13 they took to remove product from the market in 14 connection with the recall? 15 MR. VAUGHN: Objection to form. 16 A. If they were public documents, I would 17 have. But if not, if they were not public documents, 18 I would not, that's correct. So if you're referring 19 to things that were only in your discovery, then no, 20 and I haven't cited them and I would not have 21 reviewed those. 22 This also an area that I know that other 23 experts are covering in terms of actions related to 24 the recall itself, but I'm talking about something a 25 little bit more broad than that, than just a recall.</p>	<p style="text-align: right;">Page 321</p> <p>1 MR. VAUGHN: That's fine. We're going 2 to have two-and-a-half minutes left when we come 3 back. 4 VIDEOGRAPHER: Going off the record, the 5 time is 7:39 p.m., Eastern Time. This is the end of 6 media unit 6. 7 (Recess taken.) 8 VIDEOGRAPHER: We're back on the record. 9 The time is 8:03 p.m. Eastern Time, this is the 10 beginning of media unit 7. 11 EXAMINATION BY 12 MS. NAGLE: 13 Q. Hi, Dr. Plunkett. My name is Brittney 14 Nagle and I represent the Torrent Defendants in this 15 action. I have just a quick cleanup point for you. 16 So do you recall a couple of minutes ago before the 17 break, Mr. Harkins was asking you about paragraph 57 18 of your report? 19 A. Yes. 20 Q. Okay. 21 A. I don't remember the question but I 22 remember we were talking about it. 23 Q. Do you recall that he asked you whether 24 or not you had reviewed any of the recall notices or 25 the documentation on the holds that Teva had issued</p>

<p style="text-align: right;">Page 322</p> <p>1 with respect to its Valsartan?</p> <p>2 A. No.</p> <p>3 Q. And I believe that to summarize the</p> <p>4 answer you gave, you said that you reviewed</p> <p>5 everything that's listed on Exhibit C in your report,</p> <p>6 things that were publicly available to be the FDA's</p> <p>7 website, and that if it was not public, and it's not</p> <p>8 listed, you did not review it.</p> <p>9 A. In that area, that is correct.</p> <p>10 Q. Is the same true for Torrent, with</p> <p>11 respect to their recall notices and other</p> <p>12 communications about the Valsartan?</p> <p>13 A. Yes, it would be the same answer. It's</p> <p>14 not one of those listed -- I don't know whether you</p> <p>15 want to represent, but it's not, if it's not there,</p> <p>16 no, I did not.</p> <p>17 MS. NAGLE: That's the only questions</p> <p>18 that I have for you. Thank you.</p> <p>19 MR. VAUGHN: All right, Dr. Plunkett, I</p> <p>20 have just a few questions. I think we can go without</p> <p>21 a break, right?</p> <p>22 THE WITNESS: Right, that's fine, let's</p> <p>23 get it done.</p> <p>24 (Continued on following page.)</p> <p>25</p>	<p style="text-align: right;">Page 324</p> <p>1 Valsartan without access to ZHP's Drug Master File?</p> <p>2 A. The same answer. Based upon what</p> <p>3 Novartis was able to do, yes, they should have been</p> <p>4 able to do that.</p> <p>5 Q. At any point in time, if Valsartan</p> <p>6 contained NDMA, would it be deemed adulterated?</p> <p>7 A. Yes.</p> <p>8 Q. At any point in time, if Valsartan</p> <p>9 contained NDEA, would it be deemed adulterated?</p> <p>10 A. Yes, absolutely.</p> <p>11 MR. VAUGHN: I have no further</p> <p>12 questions.</p> <p>13 MS. MILLER: I will have one or two</p> <p>14 follow-up questions. I promise this break will just</p> <p>15 be three minutes.</p> <p>16 MR. VAUGHN: As long as it's just one or</p> <p>17 two, because I think, are we at seven hours on the</p> <p>18 record?</p> <p>19 MS. MILLER: We are at seven hours. We</p> <p>20 have a very long-winded witness --</p> <p>21 MR. VAUGHN: I said it's fine.</p> <p>22 VIDEOGRAPHER: All right, going off the</p> <p>23 report. The time is 8:07 p.m.</p> <p>24 (Recess taken.)</p> <p>25 VIDEOGRAPHER: We're back on the record.</p>
<p style="text-align: right;">Page 323</p> <p>1 EXAMINATION BY</p> <p>2 MR. VAUGHN:</p> <p>3 Q. Do you believe that Teva should have</p> <p>4 obtained access to ZHP's Drug Master File?</p> <p>5 A. Yes, I do.</p> <p>6 Q. Do you believe that Torrent should have</p> <p>7 obtained access to ZHP's Drug Master File?</p> <p>8 A. Yes, I do.</p> <p>9 Q. Why should the finished dose</p> <p>10 manufacturers have obtained access to ZHP's Drug</p> <p>11 Master File?</p> <p>12 A. It's the -- the only way that they would</p> <p>13 be able to assure themselves that the API company, in</p> <p>14 this case, ZHP, had done a complete and proper risk</p> <p>15 assessment, especially given that the processes had</p> <p>16 changed from the TIN process that was part of the</p> <p>17 Diovan RLD monograph.</p> <p>18 Q. In your opinion, could Teva detected</p> <p>19 have the nitrosamine impurities in ZHP's Valsartan</p> <p>20 without access to ZHP's Drug Master File?</p> <p>21 A. Yes, if they did what Novartis did,</p> <p>22 because Novartis did that. I have no information</p> <p>23 that Novartis had access to that.</p> <p>24 Q. In your opinion, could Torrent have</p> <p>25 detected the nitrosamine impurities in ZHP's</p>	<p style="text-align: right;">Page 325</p> <p>1 The time is 8:13 p.m. Eastern Time.</p> <p>2 MR. VAUGHN: Before you start, real</p> <p>3 quick, let the record reflect there is one minute</p> <p>4 remaining on the record, and we're allowing you two</p> <p>5 questions. Go ahead, Jessica.</p> <p>6 MS. MILLER: It may be three questions,</p> <p>7 Brett.</p> <p>8 MR. VAUGHN: It's over a minute, then.</p> <p>9 FURTHER EXAMINATION</p> <p>10 BY MS. MILLER:</p> <p>11 Q. Dr. Plunkett, I believe Mr. Vaughn just</p> <p>12 asked you whether at any point in time this Valsartan</p> <p>13 contained NDMA and and NDEA, would it be deemed</p> <p>14 adulterated, do you recall that question?</p> <p>15 A. Yes.</p> <p>16 Q. And your answer is yes, correct?</p> <p>17 A. Yes.</p> <p>18 Q. What do you mean by "deemed"?</p> <p>19 A. That's the regulatory language. When</p> <p>20 you talk about looking at the actual definition of</p> <p>21 "adulterated." I may be long-winded, telling you,</p> <p>22 but essentially in my report, I used that specific</p> <p>23 language.</p> <p>24 Q. Are you saying that the FDA would have</p> <p>25 deemed it adulterated, or that anyone would have</p>

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<p>1 deemed it adulterated?</p> <p>2 A. That I would deem adulterated consistent</p> <p>3 with FDA's actions that they took and their decisions</p> <p>4 that they made in 2019 when they sent the warning</p> <p>5 letter and made that statement. There is no</p> <p>6 difference in the facts then than there would have</p> <p>7 been if they looked at that issue a year earlier.</p> <p>8 Q. Are you offering --</p> <p>9 MR. VAUGHN: All right, that's a</p> <p>10 minute-and-a-half. The deposition is done.</p> <p>11 MS. MILLER: That's ridiculous, Brett.</p> <p>12 MR. VAUGHN: It's not ridiculous --</p> <p>13 MS. MILLER: -- the witness, I have a</p> <p>14 couple of more questions --</p> <p>15 MR. VAUGHN: You've asked and answered</p> <p>16 the same questions over and over. You've asked</p> <p>17 irrelevant questions about presentations. No. We</p> <p>18 started this at eight a.m. We've been going for</p> <p>19 eleven-and-a-half hours. You guys have taken massive</p> <p>20 breaks throughout the day. We're done.</p> <p>21 MS. MILLER: Are you really not going to</p> <p>22 let me finish asking these questions? Are we going</p> <p>23 to have to go to the Special Master to ask him to ask</p> <p>24 five --</p> <p>25 MR. VAUGHN: Five -- you said you -- no,</p>	<p>1 We have one question. I just want to be clear on the</p> <p>2 record.</p> <p>3 MR. VAUGHN: You guys should have</p> <p>4 reserved some time before spending all of it on your</p> <p>5 initial questions.</p> <p>6 MS. MILLER: Brett, we have a couple of</p> <p>7 follow-up questions, both from ZHP and from Teva on</p> <p>8 your redirect. Are you going to let us ask them or</p> <p>9 are we going to go to Vanaskie and come back another</p> <p>10 day? It's up to you.</p> <p>11 MR. VAUGHN: It's up to you, if you want</p> <p>12 to go to the Master. But you're not going to ask</p> <p>13 more questions today.</p> <p>14 MS. LOCKARD: That's fine, we'll go to</p> <p>15 the court. The court has already ruled that when</p> <p>16 there are multiple defendants, we have an opportunity</p> <p>17 to spend more than seven hours. There's a ruling on</p> <p>18 that already. I guess it's our mistake for not</p> <p>19 clarifying that previously, but we'll file a motion</p> <p>20 with Vanaskie tomorrow.</p> <p>21 MR. VAUGHN: Thank you, Victoria.</p> <p>22 MR. NIGH: I want to make it clear, it's</p> <p>23 Daniel Nigh for the record, that Defendants said that</p> <p>24 they had two questions before we went on a break</p> <p>25 where they said it would be a three-minute break,</p>
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<p>1 we done.</p> <p>2 MS. MILLER: I'm sorry, it was a few</p> <p>3 more than two questions, it was a few minutes. Are</p> <p>4 you really going to --</p> <p>5 MR. VAUGHN: Yes, you should have used</p> <p>6 your time a lot better throughout the day.</p> <p>7 MS. MILLER: Excuse me, Brett?</p> <p>8 MR. VAUGHN: Do you want me to repeat --</p> <p>9 MS. MILLER: You've been taking multiple</p> <p>10 expert depositions in this matter that have gone</p> <p>11 slightly over. In fact, more than slightly over, is</p> <p>12 my understanding. Are you, as part of the</p> <p>13 professional courtesy, not going to let me finish my</p> <p>14 questioning? Am I going --</p> <p>15 MR. VAUGHN: You're just going to keep</p> <p>16 going on and on, yeah.</p> <p>17 MS. MILLER: Am I going to have to go to</p> <p>18 Vanaskie?</p> <p>19 MR. VAUGHN: You should have reserved</p> <p>20 time.</p> <p>21 MS. MILLER: Brett, we have --</p> <p>22 MR. HARKINS: For the record, finished</p> <p>23 does manufacturers have one question in follow-up to</p> <p>24 an opinion that is not contained in the expert's</p> <p>25 report and was raised for the first time on redirect.</p>	<p>1 ended up being a ten-minute break. And it's getting</p> <p>2 late in the day, and at this point, two questions is</p> <p>3 now, I heard many more than two. So that agreement</p> <p>4 that the Defendants set or proffered to set, that</p> <p>5 they had two more questions, doesn't sound like they</p> <p>6 were being honest with that "two more questions."</p> <p>7 MS. MILLER: Yes, Daniel, I was being</p> <p>8 dishonest. Are you actually accusing me of</p> <p>9 dishonesty now? Because seriously, Dr. Plunkett --</p> <p>10 MR. NIGH: Well, sounds like you were</p> <p>11 inaccurate. Let's go ahead and read -- read --</p> <p>12 inaccurate about your two minutes, two questions.</p> <p>13 That was the agreement. Can you not interrupt me,</p> <p>14 please?</p> <p>15 MS. MILLER: Could you please not accuse</p> <p>16 me --</p> <p>17 MR. NIGH: Don't get into the whole</p> <p>18 dishonesty. I didn't say dishonest. I didn't -- I</p> <p>19 didn't accuse you of dishonesty, I said it wasn't</p> <p>20 honest. There's a difference between the two -- no,</p> <p>21 no I didn't.</p> <p>22 MS. MILLER: You accused me of being</p> <p>23 dishonest --</p> <p>24 MR. NIGH: I said it wasn't an honest</p> <p>25 statement --</p>

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<p>1 MS. MILLER: I did not know --</p> <p>2 MR. NIGHT: I said it was not an honest</p> <p>3 statement. To make it clear -- you keep interrupting</p> <p>4 me.</p> <p>5 MS. MILLER: Wait a minute, no. Because</p> <p>6 I -- accused of dishonesty and that is not</p> <p>7 acceptable. First of all, my first question --</p> <p>8 excuse me, you can talk after I'm done.</p> <p>9 MR. NIGH: No, no, no. No, to make it</p> <p>10 clear -- can you stop interrupting me?</p> <p>11 MS. MILLER: You're interrupting me now.</p> <p>12 My first question --</p> <p>13 MR. NIGH: To make it clear, I will</p> <p>14 change my statement to "inaccurate statement."</p> <p>15 MS. MILLER: My first question was, "Do</p> <p>16 you recall him asking you this question." Are you</p> <p>17 counting that as one of my two questions? Seriously?</p> <p>18 I was making sure that Dr. Plunkett knew where we</p> <p>19 were. That was not a question. I was completely</p> <p>20 honest and based on her answer, I had to complete the</p> <p>21 line of questioning. I had about three minutes left,</p> <p>22 at most. And you guys have decided to turn this into</p> <p>23 a world war, and that's fine. We'll go to Vanaskie,</p> <p>24 but --</p> <p>25 MR. NIGH: It's not a world war.</p>	<p>1 that one of my two questions was, "Do you recall</p> <p>2 Mr. Vaughn asking you that question," which was</p> <p>3 obviously a setup to my questioning. That was not a</p> <p>4 question. I am not -- are you guys going to require</p> <p>5 us to go to Vanaskie or not? Just let us know, or</p> <p>6 would you like to go three more minutes and be done?</p> <p>7 MR. NIGH: Even if you don't include</p> <p>8 that question or the question after it, you still</p> <p>9 would have asked two questions.</p> <p>10 MS. MILLER: Are you -- would you like</p> <p>11 to go three more minutes and be done, or go</p> <p>12 to Vanaskie? I'm asking you which you prefer.</p> <p>13 MR. NIGH: I think Mr. Vaughn has</p> <p>14 already been clear on that.</p> <p>15 MS. MILLER: Mr. Vaughn, would you like</p> <p>16 to go three more minutes and be done or do we need to</p> <p>17 go to Vanaskie?</p> <p>18 MR. VAUGHN: I think we're done. We</p> <p>19 don't compromise compromises.</p> <p>20 MS. MILLER: And you're going to deny</p> <p>21 Steve's ability to ask his questions as well?</p> <p>22 MR. NIGH: I think what we did, and</p> <p>23 Mr. Vaughn was just clear, he said you could ask two</p> <p>24 more questions based on your representation that</p> <p>25 defendants had two more questions. Period. No more</p>
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<p>1 MS. MILLER: It is 8:18 and I would have</p> <p>2 been done by 8:21. And if you're not going to let us</p> <p>3 do that, that's fine. We'll go to Vanaskie, but I</p> <p>4 would like to be clear for the record that</p> <p>5 assuming -- oh, now you're interrupting me? Assuming</p> <p>6 that Dr. Plunkett did not give one of her long-winded</p> <p>7 responses, I would have been done by 8:21.</p> <p>8 MR. VAUGHN: You've asked the same</p> <p>9 question over and over again. You would have done</p> <p>10 that, too.</p> <p>11 MS. MILLER: Thank you very much for</p> <p>12 your assessment of my questions.</p> <p>13 MR. NIGH: Let me reiterate what I said,</p> <p>14 I will reiterate what I said before we went to the</p> <p>15 break. Defense counsel said that they would have two</p> <p>16 questions. Defense counsel clearly had more than two</p> <p>17 questions, so it was an inaccurate statement. We</p> <p>18 allowed you to go forward based on your</p> <p>19 representation that you had two more questions, and</p> <p>20 the record is clear that there were clearly more than</p> <p>21 two questions. And that's when Mr. Vaughn shut down</p> <p>22 the deposition. Thank you.</p> <p>23 MS. MILLER: Everything you just said</p> <p>24 was inaccurate, and that's fine. Because I've now</p> <p>25 been accused of dishonesty. You are now telling me</p>	<p>1 than --</p> <p>2 MR. HARKINS: I represented that we had</p> <p>3 one question based on an opinion which was not</p> <p>4 offered in the witness' report or at any time during</p> <p>5 her direct testimony. It is one literal question. I</p> <p>6 understand that you were saying we will not be able</p> <p>7 to ask that, so we'll file a motion tomorrow.</p> <p>8 MS. MILLER: All right, have a good</p> <p>9 night.</p> <p>10 VIDEOGRAPHER: All right, we are off the</p> <p>11 record at 8:21 p.m. Pacific time and this -- I'm</p> <p>12 sorry, Eastern Time, and this concludes today's</p> <p>13 testimony given by Dr. Laura M. Plunkett. The total</p> <p>14 number of media used was seven and will be retained</p> <p>15 by Veritext.</p> <p>16 (Time noted: 8:21 p.m.)</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>

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1 CERTIFICATE.

2 I, DAVID LEVY, a certified court
 3 reporter and notary public of the State of New
 4 Jersey, certify that the foregoing is a true and
 5 accurate transcript of the stenographic notes of the
 6 deposition of said witness who was first duly sworn
 7 by me, on the date and place as hereinbefore set
 8 forth.

9 I FURTHER CERTIFY that I am neither
 10 attorney, nor counsel for, nor related to or employed
 11 by, any of the parties to the action in which this
 12 deposition was taken, and further that I am not a
 13 relative or employee of any attorney or counsel in
 14 this place, nor am I financially interested in this
 15 case.

16 IN WITNESS WHEREOF, I have hereunto
 17 set my hand this 17th day of January 2023.

18

19

20

21



22 DAVID LEVY, CKR, RPR, CLR

23 LICENSE NO. 30X100234000

24

25

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1 JURAT/ERRATA

2 I have read my testimony in the foregoing transcript
 3 and believe it to be true and correct with the
 4 following changes:

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22 Subscribed and sworn to before me

23 this ____ day of _____, 20____

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25 State of _____.

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Federal Rules of Civil Procedure

Rule 30

(e) Review By the Witness; Changes.

(1) Review; Statement of Changes. On request by the deponent or a party before the deposition is completed, the deponent must be allowed 30 days after being notified by the officer that the transcript or recording is available in which:

(A) to review the transcript or recording; and

(B) if there are changes in form or substance, to sign a statement listing the changes and the reasons for making them.

(2) Changes Indicated in the Officer's Certificate. The officer must note in the certificate prescribed by Rule 30(f)(1) whether a review was requested and, if so, must attach any changes the deponent makes during the 30-day period.

DISCLAIMER: THE FOREGOING FEDERAL PROCEDURE RULES ARE PROVIDED FOR INFORMATIONAL PURPOSES ONLY.

THE ABOVE RULES ARE CURRENT AS OF APRIL 1, 2019. PLEASE REFER TO THE APPLICABLE FEDERAL RULES OF CIVIL PROCEDURE FOR UP-TO-DATE INFORMATION.

VERITEXT LEGAL SOLUTIONS
COMPANY CERTIFICATE AND DISCLOSURE STATEMENT

Veritext Legal Solutions represents that the foregoing transcript is a true, correct and complete transcript of the colloquies, questions and answers as submitted by the court reporter. Veritext Legal Solutions further represents that the attached exhibits, if any, are true, correct and complete documents as submitted by the court reporter and/or attorneys in relation to this deposition and that the documents were processed in accordance with our litigation support and production standards.

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